Proposed Registration Decision PRD2014-08

Aminocyclopyrachlor

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Overview

Proposed Registration Decision for Aminocyclopyrachlor

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of Aminocyclopyrachlor Technical and DPX-MAT 28 Herbicide, Truvist Herbicide, Navius Herbicide and Rejuvra XL Herbicide, containing the technical grade active ingredient aminocyclopyrachlor, to control or suppress several broadleaved weeds and woody plant species in pastures, rangelands and various non-crop sites.

An evaluation of available scientific information found that, under the approved conditions of use, the products have value and do not present an unacceptable risk to human health or the environment.

This Overview describes the key points of the evaluation, while the Science Evaluation section provides detailed technical information on the human health, environmental and value assessments of aminocyclopyrachlor and its associated end-use products.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[1] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its proposed conditions of registration. The Act also requires that products have value[2] when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

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1 "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act.*

2 "Value" as defined by subsection 2(1) of the *Pest Control Products Act*: "the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact."

Before making a final registration decision on aminocyclopyrachlor, the PMRA will consider all comments received from the public in response to this consultation document.[3] The PMRA will then publish a Registration Decision[4] on aminocyclopyrachlor, which will include the decision, the reasons for it, a summary of comments received on the proposed final registration decision and the PMRA's response to these comments.

For more details on the information presented in this Overview, please refer to the Science Evaluation section of this consultation document.

What Is Aminocyclopyrachlor?

Aminocyclopyrachlor is a herbicide that belongs to the new class of chemistry known as the pyrimidine carboxylic acids. This compound mimics auxin, which is a naturally occurring phytohormone. Aminocyclopyrachlor is readily absorbed by the foliage and roots and is translocated in both xylem and phloem to meristematic regions. This herbicide is translocated to a greater extent in susceptible broadleaved species than in the more tolerant grasses.

Aminocyclopyrachlor is the active ingredient in DPX-MAT 28 Herbicide and one of the two active ingredients in each of Truvist Herbicide, Navius Herbicide and Rejuvra XL Herbicide.

Health Considerations

Can Approved Uses of Aminocyclopyrachlor Affect Human Health?

Products containing aminocyclopyrachlor are unlikely to affect your health when used according to label directions.

Potential exposure to aminocyclopyrachlor may occur through the diet (food and water) or when handling and applying the end-use products DPX-MAT 28 Herbicide, Truvist Herbicide, Navius Herbicide, and Rejuvra XL Herbicide. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed. The health effects noted in animals occur at doses more than 100-times higher (and often much higher) than levels to which humans are normally exposed when pesticide products are used according to label directions.

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

In laboratory animals, the technical grade active ingredient, aminocyclopyrachlor, was of low acute toxicity via the oral, dermal and inhalation routes of exposure. Aminocyclopyrachlor was minimally irritating to the eyes and slightly irritating to the skin and did not cause an allergic skin reaction.

The acute toxicity of the end-use product, DPX-MAT 28 Herbicide, was low via the oral, dermal and inhalation routes of exposure. It was minimally irritating to the skin and did not cause an allergic skin reaction. DPX-MAT 28 Herbicide was mildly irritating to the eyes; consequently, the hazard signal words "CAUTION – EYE IRRITANT" are required on the label.

The acute toxicity of the end-use products Truvist Herbicide, Navius Herbicide and Rejuvra XL Herbicide was low via the oral, dermal and inhalation routes of exposure. Truvist Herbicide and Navius Herbicide were minimally irritating to the skin while Rejuvra XL Herbicide was non-irritating to the skin. They were minimally irritating to the eyes and did not cause allergic skin reactions.

There was no indication that aminocyclopyrachlor caused damage to the nervous system or immune system, or that it targeted any specific organ system. Aminocyclopyrachlor did not cause birth defects in animals and there were no effects on the ability to reproduce. General toxicity in the form of decreased body weight gain was observed. There was no evidence to suggest that aminocyclopyrachlor damaged genetic material. Brain tumours observed in male in rats following prolonged exposure to high doses could not be clearly ascribed to treatment with aminocyclopyrachlor.

When aminocyclopyrachlor was given to pregnant or nursing animals, no effects on the developing fetus or juvenile animal were observed, indicating that the young do not appear to be more sensitive to aminocyclopyrachlor than the adult animal.

The risk assessment protects against the effects of aminocyclopyrachlor by ensuring that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests.

Residues in Water and Food

Dietary risks from food and water are not of concern.

Chronic aggregate dietary intake estimates (food plus water) revealed that the general population and infants less than one year old, the subpopulation that would ingest the most aminocyclopyrachlor relative to body weight, are expected to be exposed to less than 1% of the acceptable daily intake. Based on these estimates, the chronic dietary risk from aminocyclopyrachlor is not of concern for all population subgroups. There were no cancer risks of concern for aminocyclopyrachlor.

Animal studies revealed no acute health effects. Consequently, a single dose of aminocyclopyrachlor is not likely to cause acute health effects in the general population (including infants and children).

The *Food and Drugs Act* prohibits the sale of adulterated food, that is, food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Residue trials conducted throughout Canada and the United States using aminocyclopyrachlor methyl ester on grass were acceptable. The MRLs for aminocyclopyrachlor can be found in the Science Evaluation section of this Consultation Document.

The use of metsulfuron-methyl (on pasture and rangeland) in a co-formulation with aminocyclopyrachlor is acceptable as this active ingredient is registered for use in Canada with similar application rates and restrictions. The uses were previously assessed and are considered to be not of health concern.

Occupational Risks From Handling DPX-MAT 28 Herbicide, Truvist Herbicide, Navius Herbicide and Rejuvra XL Herbicide.

Occupational risks are not of concern when DPX-MAT 28 Herbicide, Truvist Herbicide, Navius Herbicide and Rejuvra XL Herbicide are used according to the proposed label directions, which include protective measures.

Farmers and custom applicators who mix, load or apply DPX-MAT 28 Herbicide, Truvist Herbicide, Navius Herbicide or Rejuvra XL Herbicide, as well as field workers re-entering pasture, rangeland and non-crop areas can come in direct contact with aminocyclopyrachlor residues on the skin. Therefore, the label specifies that anyone mixing/loading and applying must wear a long-sleeved shirt, long pants, shoes, socks and chemical-resistant gloves (gloves not required for groundboom application). The label also requires that workers do not enter treated areas for 12 hours after application for agricultural uses and until residues have dried for non-agricultural scenarios. Taking into consideration these label statements, the number of applications and the expectation of the exposure period for handlers and workers, the risks to these individuals are not a concern. There were no cancer risks of concern.

Truvist Herbicide is a co-formulation with chlorsulfuron, and Navius Herbicide and Rejuvra XL Herbicide are co-formulations with metsulfuron-methyl. Chlorsulfuron and metsulfuron-methyl are registered for use on pasture, rangeland and non-crop areas in Canada. The precautions required to mitigate risk from the exposure of aminocyclopyrachlor are also adequate for the co-formulated active ingredients.

For bystanders, exposure is expected to be much less than that for workers and is considered negligible. Therefore, health risks to bystanders are not of concern.

Environmental Considerations

What Happens When Aminocyclopyrachlor Is Introduced into the Environment?

Aminocyclopyrachlor is toxic to non-target terrestrial plants including coniferous and deciduous trees. It is moderately persistent to persistent in aerobic soil and persistent in anaerobic soil and aquatic systems. Aminocyclopyrachlor is a potential leacher and may reach groundwater. Precautionary label statements, as well as buffer zones, are required.

When aminocyclopyrachlor is applied using ground or aerial application methods to rights-of-way, pastures and rangelands, some of it will enter into soil and it also has the potential to enter water through spray drift, leaching and surface runoff. It also has the potential to be redistributed in the environment through compost products containing treated plant materials and in animal manure.

Aminocyclopyrachlor is very soluble in water. In soil, it does not breakdown very rapidly, is likely to be persistant, and does not form any major transformation products. Laboratory and field studies indicate that aminocyclopyrachlor will move through the soil profile and has the potential to leach to groundwater. In the aquatic environment, aminocyclopyrachlor is expected to predominantly remain in the water layer. Chemically, it does not breakdown through hydrolysis; however, it can breakdown through photransformation in water where light can penetrate. Laboratory soil studies and terrestrial field dissipation studies indicate slow microbial degradation. Aminocyclopyrachlor is not expected to appreciably bioconcentrate in fish. It is not volatile and therefore not expected to be subject to long-range transport in the air.

There is the potential for non-target terrestrial and aquatic habitats to be exposed to the chemical as a result of spray drift or runoff. Aminocyclopyrachlor is not expected to pose a risk to most terrestrial and aquatic organisms when used according to the label. However, although it can present a risk to terrestrial plants, including coniferous and deciduous trees, the risk is mitigated by label statements.

The combination products Truvist Herbicide, Navius Herbicide and Rejuvra XL Herbicie also contain chlorsulfuron or metsulfuron-methyl. Chlorsulfuron and metsulfuron-methyl are toxic to freshwater organisms and non-target terrestrial plants, as previously described in Re-evaluation Decision RVD-2008-08, *Chlorsulfuron* and Re-evaluation Decision RVD2008-35, *Metsulfuron-methyl*, respectively. Statements on the product labels are required to inform users of the toxicity of these products.

Value Considerations

What Is the Value of Aminocyclopyrachlor?

Herbicide products containing aminocyclopyrachlor, either as the lone active ingredient (DPX-MAT 28 Herbicide for use in pasture, rangeland and non-crop areas) or formulated with a second active ingredient belonging to the sulfonylurea chemical family, specifically

chlorsulfuron (Truvist Herbicide for use in non-crop areas) or metsulfuron-methyl (Navius Herbicide for use in rangeland and non-crop areas or Rejuvra XL Herbicide for use in pasture, rangeland and non-crop areas) are applied postemergence to weeds and undesirable brush with efficacy claims being specific to product and application rate.

Aminocyclopyrachlor may contribute to resistance management in the same manner as other synthetic auxin herbicides Weed Science Society of America (WSSA) Group 4 herbicides) registered for use in pasture, rangeland and non-crop areas. For the three pre-mix products, aminocyclopyrachlor may reduce the potential for the development of resistance to WSSA Group 2 herbicides, which include sulfonylureas, since aminocyclopyrachlor has herbicidal activity on many of the same weeds that are normally susceptible to the Group 2 active ingredient contained in these products.

The value of the three co-formulated end-use products essentially relates to an increased weed spectrum as compared to other registered Group 2 and Group 4 herbicides applied alone in pasture, rangeland and non-crop areas, and to their contribution to resistance management.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of DPX-MAT 28 Herbicide, Truvist Herbicide, Navius Herbicide and Rejuvra XL Herbicide to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

Because there is a concern with users coming into direct contact with aminocyclopyrachlor on the skin or through inhalation of spray mists, anyone mixing, loading and applying DPX-MAT 28 Herbicide, Truvist Herbicide, Navius Herbicide or Rejuvra XL Herbicide must wear a long-sleeved shirt, long pants, shoes, socks and chemical-resistant gloves (gloves not required for groundboom application).

The labels also require that workers do not enter treated areas for 12 hours after application for agricultural uses and until residues have dried for non-agricultural scenarios. In addition, standard label statements to protect against drift during application were added to the label.

Environment

Aminocyclopyrachlor can pose a risk to non-target terrestrial plants and there is uncertainty related to the potential effects on non-target trees when this herbicide is used in pastures and

rangelands. Label statements informing the users of the potential risks to these woody species are specified on the product labels. To mitigate potential exposure via spray drift, spray buffer zones of 5 to 225 metres are required to protect sensitive terrestrial habitats, and must be specified on the product labels.

The second active ingredients (chlorsulfuron in Truvist Herbicide or metsulfuron-methyl in Navius Herbicide and Rejuvra XL Herbicide) can pose a risk to freshwater organisms in addition to non-target terrestrial plants. Statements on the product labels are required to inform users of the toxicity to these organisms. In order to minimize the potential for exposure resulting from off-field drift, spray buffer zones of 20 to 800 meters and 1 to 250 meters will be required between the treated area and downwind terrestrial and freshwater habitats, respectively.

Aminocyclopyrachlor has the potential to leach to groundwater. Label statements informing the users of the leaching potential of this chemical are to be specified on the product labels.

Aminocyclopyrachlor has the potential to enter the environment from compost products containing treated plant materials and animal manure. Statements informing the users to avoid the entry of treated material into compost products are to be specified on the product labels.

Next Steps

Before making a final registration decision on aminocyclopyrachlor, the PMRA will consider all comments received from the public in response to this consultation document. The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (contact information on the cover page of this document). The PMRA will then publish a Registration Decision, which will include its decision, the reasons for it, a summary of comments received on the proposed final decision and the Agency's response to these comments.

Other Information

When the PMRA makes its registration decision, it will publish a Registration Decision on aminocyclopyrachlor (based on the Science Evaluation section of this consultation document). In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa).

Science Evaluation

Aminocylcopyrachlor

1.0 The Active Ingredient, Its Properties and Uses

1.1 Identity of the Active Ingredient

Active substance aminocyclopyrachlor

Function Herbicide

Chemical name

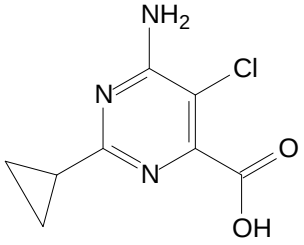
1. **International Union of Pure and Applied Chemistry (IUPAC)** 6-amino-5-chloro-2-cyclopropylpyrimidine-4-carboxylic acid
2. **Chemical Abstracts Service (CAS)** 6-amino-5-chloro-2-cyclopropyl-4-pyrimidinecarboxylic acid

CAS number 858956-08-8

Molecular formula $C_8H_8ClN_3O_2$

Molecular weight 213.62

Structural formula



Purity of the active ingredient 91.2%

1.2 Physical and Chemical Properties of the Active Ingredients and End-use Product

Technical Product—Aminocyclopyrachlor Technical

Property	Result
Colour and physical state	White solid
Odour	Mild fruity odour at room temperature
Melting range	138.9±0.1°C
Boiling point or range	N/A

Property	Result
Density	0.67 g/cm^3
Vapour pressure	Temp (°C) / Vapour Pressure (10^{-6} Pa) 40.0 — 2.1111 45.0 — 1.0799 50.0 — 1.1694 20 — 6.9215 (calculated) 25 — 4.9113 (calculated)
Henry's law constant at 20°C and pH 7	3.47×10^{-12} atm/m^3/mol
Ultraviolet (UV)-visible spectrum	pH / λ (nm) / ε (L mol^{-1} cm^{-1}) 1.8 — 220 — 21591.8 7.0 — 285, 240, 210[max] — 26009.1 10.5 — 285, 240, 210[max] — 25628.1 not expected to absorb at λ > 300 nm
Solubility in water at 20°C	Media / Solubility (g/L) Milli-Q water — 2.81 Buffer (pH 4) — 3.13 Buffer (pH 7) — 4.20 Buffer (pH 9) — 3.87
Solubility in organic solvents	Solvent / Solubility (g/L) methanol — 36.747 ethyl acetate — 2.008 n-octanol — 1.945 acetone — 0.960 acetonitrile — 0.651 dichloromethane — 0.235 o-xylene — 0.005 n-hexane — 9.7E-06
n-Octanol–water partition coefficient (K_{ow})	pH / log K_{ow} 4 — -1.01 7 — -2.48 The active was not detected in n-octanol phase at pH 9 due to its high water solubility. Consequently log K_{ow} at pH 9 was not calculated.
Dissociation constant (pK_a)	4.65 at 20°C
Stability (temperature, metal)	The product is stable at room temperature and at 54°C for 14 days. It is also stable for 14 days in contact with metals iron and aluminum, iron (II) acetate and aluminum acetate.

End-use Product—DPX-MAT 28 Herbicide

Property	Result
Colour	Cream
Odour	Faint, ammonia-like odour
Physical state	Solid
Formulation type	Soluble granule (SG)
Guarantee	50%
Container material and description	Plastic or paper, jug, bottle or bag, 60 g – bulk
Density at 20°C	0.50–0.56 g/cm^3
pH of 1% dispersion in water	6.3
Oxidizing or reducing action	The product does not contain any oxidizing or reducing agents.
Storage stability	The product is stable when stored in HDPE container at warehouse conditions for 1 year.
Corrosion characteristics	No corrosion to HDPE container was observed during 1 year commercial storage.
Explodability	The product is not explosive.

End-use Product—Truvist Herbicide

Property	Result
Colour	Blend of cream and light brown
Odour	Faint, ammonia-like odour
Physical state	Solid
Formulation type	Wettable granule (WG)
Guarantee	Aminocyclopyrachlor … 39.5%, Chlorsulfuron … 15.8%
Container material and description	Plastic or paper, jug, bag or supersack, 1 kg – bulk
Density at 20°C	0.50–0.56 g/cm^3
pH of 1% dispersion in water	5.6
Oxidizing or reducing action	The product does not contain any oxidizing or reducing agents.
Storage stability	The product is stable in HDPE containers for 1 year at room temperature.
Corrosion characteristics	No corrosion to HDPE containers during 1 year storage at ambient temperature.
Explodability	The product is not expected to be explosive.

End-use Product—Navius Herbicide

Property	Result
Colour	Blend of cream and light brown
Odour	Faint, ammonia-like odour
Physical state	Solid
Formulation type	Wettable granule (WG)
Guarantee	Aminocyclopyrachlor … 39.5%, Metsulfuron-methyl … 12.6%
Container material and description	Plastic or paper, jug, bag or supersack, 1 kg – bulk
Density at 20°C	0.50–0.56 g/cm^3
pH of 1% dispersion in water	5.7
Oxidizing or reducing action	The product does not contain any oxidizing or reducing agents.
Storage stability	The product is stable to HDPE containers at ambient temperature for 1 year.
Corrosion characteristics	No corrosion to HDPE containers was observed during 1 year storage at ambient temperature.
Explodability	The product is not expected to be explosive.

End-use Products—Rejuvra XL Herbicide

Property	Result
Colour	Blend of brown and off-white
Odour	No characteristic odour
Physical state	Solid
Formulation type	Wettable granule (WG)
Guarantee	Aminocyclopyrachlor … 35.3%, Metsulfuron-methyl … 17.6%
Container material and description	plastic/paper jug/bag/supersack, 1 kg – bulk
Density at 20°C	0.7014 g/cm^3
pH of 1% dispersion in water	6.18
Oxidizing or reducing action	The product does not contain any oxidizing or reducing agents.
Storage stability	The product is stable for one year stored in HDPE container at ambient temperature.
Corrosion characteristics	No corrosion to HDPE container was observed during one year storage at ambient temperature.
Explodability	The product is not expected to be explosive.

1.3 Directions for Use

1.3.1 DPX-MAT 28 Herbicide

DPX-MAT 28 Herbicide, a soluble granule formulation containing 50% aminocyclopyrachlor, present as the acid, is applied to emerged actively growing weeds at 30, 35, or 70 g a.i./ha, equivalent to 60, 70, and 140 g product/ha, respectively, in combination with a surfactant (a non-ionic surfactant at 0.25% v/v, or 1% v/v of a crop oil concentrate or Merge Adjuvant (Registration Number 24702) by means of ground or aerial application equipment in pasture, rangeland and non-crop areas, such as utility rights of way, roadsides, industrial sites and fencelines, for the control or suppression of several broadleaved weed species as well as particular woody species. DPX-MAT 28 Herbicide may also be used as a component of integrated vegetation management programs aimed at controlling particular invasive weeds. The maximum annual application rate of 70 g a.i./ha allows for a maximum of one application at the highest rate or two applications at the lower rates.

1.3.2 Truvist Herbicide

Truvist Herbicide, a dispersible granule formulation containing 39.5% aminocyclopyrachlor, present as the acid, and 15.8% chlorsulfuron, is applied to emerged actively growing weeds and brush at 92.9 g a.i./ha (168 g product/ha) in combination with a surfactant (a non-ionic surfactant at 0.25% v/v, or 1% v/v of a crop oil concentrate or Merge Adjuvant) by means of ground equipment on non-crop sites of private, public and military lands for the control or suppression of an array of broadleaved weeds and some woody plant species. These non-crop sites would include uncultivated non-agricultural areas, such as airports, highway, railroad and utility rights-of-way, and sewage disposal areas, as well as uncultivated agricultural areas, such as farmyards, fuel storage areas, fence rows, non-irrigation ditchbanks, and barrier strips. Application is made typically in June or July when target weeds are young and actively growing, Truvist Herbicide may also be used as a component of invasive species management programs aimed at controlling particular invasive weeds. A maximum of one application per year may be made.

1.3.3 Navius Herbicide

Navius Herbicide, a dispersible granule formulation containing 39.5% aminocyclopyrachlor, present as acid, plus 12.6% metsulfuron-methyl, is applied to emerged actively growing weeds and brush at 87, 174, 260 or 348 g a.i./ha, equivalent to 167, 334, 499 and 668 g product/ha, in combination with a surfactant (a non-ionic surfactant at 0.25% v/v, or 1% v/v of a crop oil concentrate or Merge Adjuvant) by means of ground or aerial application equipment in rangeland and non-crop areas, such as utility rights of way, roadsides, industrial sites and fencelines, for the control or suppression of an array of annual, biennial and perennial broadleaved weeds as well as deciduous and conifer brush. The weed and brush species controlled or suppressed is specific to rate. Navius Herbicide may also be used as a component of integrated vegetation management programs aimed at controlling particular invasive weeds. The maximum annual application rate of 348 g a.i./ha allows for a maximum of one application at the highest rate or up to four applications at the lowest rate.

1.3.4 Rejuvra XL Herbicide

Rejuvra XL Herbicide, a wettable granule formulation containing 35.3% aminocyclopyrachlor, present as the acid, and 17.6% metsulfuron-methyl, is applied to emerged actively growing weeds and brush at either 45 g a.i./ha (85 g product/ha) or 90 g a.i./ha (170 g product/ha) in combination with a surfactant (a non-ionic surfactant at 0.25% v/v, or 1% v/v of a crop oil concentrate or Merge Adjuvant) by means of ground or aerial application equipment in pasture, rangeland and non-crop areas, such as utility rights of way, roadsides, industrial sites and fencelines, for the control or suppression of an array of annual, biennial and perennial broadleaved weeds as well as particular woody species. Rejuvra XL Herbicide may also be used as a component of integrated vegetation management programs aimed at controlling particular invasive weeds. The maximum annual application rate of 90 g a.i./ha allows for a maximum of one application at the higher rate or two applications at the lower rate.

1.4 Mode of Action

Aminocyclopyrachlor is a herbicide that belongs to the new class of chemistry known as the pyrimidine carboxylic acids. This compound mimics a naturally occurring phytohormone, indole acetic acid or auxin. Aminocyclopyrachlor, like most other synthetic auxins, is readily absorbed by foliage and roots and is translocated in both xylem and phloem to meristematic regions. This herbicide is translocated to a greater extent in susceptible broadleaved species than in the more tolerant grasses. As a synthetic auxin, aminocyclopyrachlor upsets the natural hormone balance such that critical growth processes that are required for cell division and elongation and protein synthesis are disrupted. Susceptible broadleaved species exhibit growth abnormalities, particularly on new growth, such as stem twisting, stunted root growth, and leaf malformations, for example, parallel venation, crinkling, and cupping.

Metsulfuron-methyl and chlorsulfuron are Weed Science Society of America (WSSA) Group 2 herbicides that belong to the sulfonylurea chemical family. Sulfonylurea herbicides are systemic in that they are taken up by both foliage and roots and translocated in xylem and phloem. Sulfonylurea herbicides inhibit acetolactate synthase (ALS), an enzyme that is required in the synthesis of branched chain amino acids: leucine, isoleucine and valine that are essential in protein synthesis and the formation of new cells. These herbicides lead to the rapid cessation of plant cell division and growth. Susceptible weeds and brush may exhibit stunting, interveinal chlorosis, red venation, purpling, and discoloration at the growing point.

2.0 Methods of Analysis

2.1 Methods for Analysis of the Active Ingredient

The methods provided for the analysis of the active ingredient and the impurities in Aminocyclopyrachlor Technical have been validated and assessed to be acceptable for the determinations.

2.2 Method for Formulation Analysis

The methods provided for the analysis of the active ingredients in the formulations have been validated and assessed to be acceptable for use as enforcement analytical methods.

2.3 Methods for Residue Analysis

High performance liquid chromatography methods with tandem mass spectrometry (HPLC-MS/MS; Method DuPont-22582 SU1 RV2 in plant matrices and Method DuPont-27162 in animal matrices) were developed and proposed for data generation purposes in grass commodities and for data generation and enforcement purposes in animal commodities. These methods fulfilled the requirements with regards to specificity, accuracy and precision at the respective method limit of quantitation. Acceptable recoveries (70–120%) were obtained in plant and animal matrices. The proposed enforcement method for animals was successfully validated in bovine liver, milk, and eggs by an independent laboratory. Adequate extraction efficiencies were demonstrated using radiolabelled grass and goat tissue samples analyzed within the metabolism studies.

Gas chromatography (GC-MS), liquid chromatography (LC-MS) and HPLC-MS/MS were developed and proposed for data generation and enforcement purposes. These methods fulfilled the requirements with regards to selectivity, accuracy and precision at the respective method limit of quantitation. Acceptable recoveries (70–120%) were obtained in plant and animal matrices and environmental media. Methods for residue analysis are summarized in Appendix I, Table 1.

3.0 Impact on Human and Animal Health

3.1 Toxicology Summary

A detailed review of the toxicological database for aminocyclopyrachor was conducted. The database is complete, consisting of the full array of toxicity studies currently required for hazard assessment purposes. The studies were carried out in accordance with currently accepted international testing protocols and Good Laboratory Practices. The scientific quality of the data is high and the database is considered adequate to define the majority of the toxic effects that may result from exposure to aminocyclopyrachor.

Absorption and excretion of single low and high or repeat low oral doses of radiolabeled aminocyclopyrachlor was rapid in both sexes of rats. Absorption ranged from 42-60%, with the single low dose accounting for slightly higher absorption. There were minimal differences between the sexes. Most of the administered dose (AD) was eliminated in the excreta within 24 hours, with elimination essentially completed by 7 days. The fecal route was the predominant route of excretion (58–69%). Bile excretion accounted for less than 1% of the AD. Urinary excretion was 22–35% of AD. The half-life in plasma was approximately 6 hours in the low and high dose groups. The time to peak concentration in blood and plasma was 1 hour in both groups. Total terminal residues 7 days postadministration accounted for trace amounts of the

administered dose, with the highest levels of radiolabel found in the gastrointestinal tract and the residual carcass. Aminocyclopyrachlor was excreted unchanged.

In the rat, the acute toxicity of aminocyclopyrachlor was low via the oral, dermal and inhalation routes of exposure. Aminocyclopyrachlor was minimally irritating to the eyes and slightly irritating to the skin of rabbits and was not a dermal sensitizer in mice.

The acute toxicity of the end-use product DPX-MAT 28 Herbicide was low in the rat via the oral, dermal and inhalation routes of exposure. It was minimally irritating to the skin and mildly irritating to the eyes of rabbits and was not a dermal sensitizer in mice.

The acute toxicity of the end-use products Truvist Herbicide, Navius Herbicide and Rejuvra XL Herbicide was low in rats via the oral, dermal and inhalation routes of exposure. They were minimally or non-irritating to the skin and minimally irritating to the eyes of rabbits and were not dermal sensitizers in mice.

Short-term repeat dose feeding studies in mice, rats and dogs with aminocyclopyrachlor revealed the rat to be the most sensitive species with decreased body weight, body weight gain, food consumption and food efficiency. The dog and mouse repeat dose feeding studies resulted in no adverse effects being observed at the limit dose. In a repeat dose dermal toxicity study with the rat, no treatment-related effects were observed up to and including the limit dose, although slight dermal irritation was observed in a few animals at the two highest doses.

Aminocyclopyrachlor was administered in the diet of mice and rats in long-term studies. In the mouse study no adverse effects were observed up to and including the limit dose. In the rat study, administration of aminocyclopyrachlor resulted in decreased body weight, body weight gain and food efficiency. Additionally, a statistically significant increase in brain astrocytomas, and astrocytomas, gliomas and oligodendrogliomas combined, was observed in males at the highest dose. None of these tumours were observed in the controls or low doses, while a single observation each of an astrocytoma and an oligodendroglioma was observed at the second highest dose. Limited appropriate historical control data were available; however, the incidence in astrocytomas was not increased beyond the historical controls, although the incidence in the high dose group was at the upper end of the historical control data. As the combined incidence of astrocytomas, gliomas and oligodendrogliomas was slightly outside the historical control range at the high dose, a Weight-of-Evidence (WOE) approach was employed to assess whether the tumours were spontaneous or treatment related. This analysis indicated that the time of tumour onset was within the normal range for these types of tumours and that there was no trend toward undifferentiated tumours, presence of preneoplastic lesions, induction of multiplicity of tumours in individual animals or induction of peripheral nervous system tumours or tumours outside of the nervous system. There was no evidence of genotoxiciy in the database. It should also be noted that the high dose was close to the limit dose for oncogenicity studies. Based on these considerations, the PMRA concluded that the increased incidence of these tumours was equivocal. Overall, the endpoints selected for risk assessment are considered protective of this effect.

When tested in the rat, aminocyclopyrachlor did not affect reproductive performance or the reproductive system, nor was there evidence of developmental toxicity. Decreases in body weight and body weight gain were seen in the P and F1 parental males in the two highest doses and a decrease in absolute and relative brain weight was seen in P females at the highest dose. Offspring exhibited decreased body weight and body weight gain at the two highest doses tested. There was no maternal or offspring toxicity observed in the rat developmental toxicity study at up to and including the limit dose. In the rabbit developmental toxicity study, maternal toxicity included decreased body weight gain and food consumption in the two highest doses tested and late occurring abortions and mortality in the limit dose. No adverse effects were observed in the offspring with the exception of the abortions at the high (limit) dose.

Aminocyclopyrachlor was tested for potential genotoxic activity in a range of in vitro and in vivo assays. Based on the uniformly negative results of these studies, aminocyclopyrachlor was not genotoxic.

The immunotoxic potential of aminocyclopyrachlor following short-term dietary dosing was examined in rats and mice. There was no evidence of immunotoxicity in either species at the limit dose.

There was no evidence of neurotoxicity in rats following short-term dietary dosing. Decreased body weight, body weight gains and food consumption were the only effects observed.

Results of the toxicology studies conducted on laboratory animals with aminocyclopyrachlor and its associated end-use products are summarized in Appendix I, Tables 2 and 3. The toxicology endpoints for use in the human health risk assessment are summarized in Appendix I, Table 4.

Incident Reports

Since 26 April 2007, registrants have been required by law to report incidents, including adverse effects to health and the environment, to the PMRA within a set time frame. Information on the reporting of incidents can be found on the PMRA website. Incidents from Canada and the United States were searched for aminocyclopyrachlor, and any additional information submitted by the applicant during the review process was considered. As of March 5, 2013, there were no health-related incident reports for this active ingredient.

3.1.1 PCPA Hazard Characterization

For assessing risks from potential residues in food or from products used in or around homes or schools, the *Pest Control Products Act* requires the application of an additional 10-fold factor to threshold effects to take into account completeness of the data with respect to the exposure of, and toxicity to, infants and children, and potential prenatal and postnatal toxicity. A different factor may be determined to be appropriate on the basis of reliable scientific data.

With respect to the completeness of the toxicity database as it pertains to the toxicity to infants and children, extensive data were available for aminocyclopyrachlor. The database contains the

full complement of required studies including developmental toxicity studies in rats and rabbits and a reproductive toxicity study in rats.

With respect to potential prenatal and postnatal toxicity, there was no indication of increased susceptibility of fetuses or offspring compared to parental animals in the reproductive and prenatal developmental toxicity studies. In pups, decreased body weight and body weight gain were observed in the reproductive toxicity study. No adverse effects were observed in the rat developmental toxicity study. In the rabbit developmental toxicity study, late occurring abortions were observed at the limit dose of testing. Maternal animals displayed decreased body weight gain and food consumption and mortality at this dose. Overall, endpoints in the young were well-characterized and occurred at doses well above those used for regulatory purposes. On the basis of this information, the PCPA factor was reduced to 1-fold.

3.2 Acute Reference Dose

As there were no effects in the toxicological database attributable to a single exposure of aminocyclopyrachlor, an acute reference dose was not established.

3.3 Acceptable Daily Intake (ADI)

To estimate risk of repeat dietary exposure, the rat two-generation reproductive toxicity study with a no observed adverse effect level (NOAEL) of 109 mg/kg bw/day was selected. At the lowest observed adverse effect level (LOAEL) of 363 mg/kg bw/day, decreased body weight and body weight gain in parental males of both generations were observed. This study provides the lowest NOAEL in the database. Standard uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies variability have been applied. As discussed in the PCPA Hazard Characterization section, the PCPA factor has been reduced to 1-fold. **The composite assessment factor (CAF) is 100**.

The ADI is calculated according to the following formula:

$$\text{ADI} = \frac{\text{NOAEL}}{\text{CAF}} = \frac{109 \text{ mg/kg bw/day}}{100} = 1.1 \text{ mg/kg bw/day of aminocyclopyrachlor}$$

The ADI provides a margin of 917 to the NOAEL for abortions in the rabbit developmental toxicity study and a margin of 870 to the high dose for male rats, at which an equivocal increase in combined astorcytomas, gliomas and oligodendrogliomas was observed.

Cancer Assessment

As discussed under Section 3.1, brain tumours were observed in male rats at the high dose in an oncogenicity study. These tumours are considered equivocal based on the WOE. Overall, the endpoints selected for non-cancer risk assessment are protective of the equivocal findings in the male rat.

3.4 Exposure from Drinking Water

3.4.1 Concentrations in Drinking Water

Expected environmental concentrations (EECs) in surface water were calculated using the PRZM/EXAMS models on standard Level 1 scenarios, a small reservoir and a prairie dugout. EECs in groundwater were calculated using the PRZM-GW model. Model simulations were conducted using conservative assumptions with respect to environmental fate, application rate and timing, and geographic scenario. All scenarios were run using 50-year weather data. The maximum yearly application rate of aminocyclopyrachlor is associated with the use of Navius Herbicide at a single application of 264 g a.i./ha. The typical dates of first application for all uses, ranged from June through mid-August therefore, the starting dates used in the models were chosen accordingly.

The highest EECs of aminocyclopyrachlor in potential drinking water sources are presented in Table 3.4.1.1. The highest groundwater EECs from specific pasture, rangeland and non-crop area use scenarios are presented in Table 3.4.1.2. Details of water modelling inputs and calculations are available upon request.

Table 3.4.1.1 Standard Level 1 Estimation of Environmental Concentrations of Aminocyclopyrachlor in Potential Sources of Drinking Water

Application Rate	Groundwater (µg a.i./L)		Surface Water (µg a.i./L)			
			Reservoir		Dugout	
	Daily[1]	Yearly[2]	Daily[3]	Yearly[4]	Daily[3]	Yearly[4]
264 g a.i./ha	592	588	14	2.1	36	29

[1] 90th percentile of daily average concentrations
[2] 90th percentile of yearly average concentrations
[3] 90th percentile of yearly peak concentrations
[4] 90th percentile of yearly average concentrations

Table 3.4.1.2 90th Percentile Groundwater EECs (µg a.i./l) from PZRM-GW Modelling of Aminocyclopyrachlor for Pasture, Rangeland and Non-Crop Area Use

Scenario	Daily	Yearly	Post Breakthrough average
Pasture and rangeland	56	55	44

3.5 Occupational and Residential Risk Assessment

3.5.1 Toxicological Endpoints

Short- and Intermediate-Term Dermal

For short- and intermediate-term occupational dermal risk assessment, a NOAEL of 1000 mg/kg bw/day (limit dose) from the dermal toxicity study in the rat was selected. This study was selected as it encompasses the relevant route of exposure and is of an appropriate duration.

The target margin of exposure (MOE) is 100. Ten-fold factors were applied each for interspecies extrapolation and intraspecies variability. This target MOE is considered to be protective of all individuals including nursing infants and the unborn children of exposed female workers.

Short- and Intermediate-Term Inhalation

For short- and intermediate-term occupational inhalation risk assessment, a NOAEL of 109 mg/kg bw/day from the reproductive toxicity study in the rat was selected. At the LOAEL of 363 mg/kg bw/day decreases in body weight and body weight gain were observed in adult males. This study was selected as it encompassed the relevant duration of exposure as no study was available by the appropriate route.

The target MOE is 100. Ten-fold factors were applied each for interspecies extrapolation and intraspecies variability. This target MOE is considered to be protective of all individuals including nursing infants and the unborn children of exposed female workers.

3.5.1.1 Dermal Absorption

Dermal absorption data were not submitted for aminocyclopyrachlor. However, the dermal toxicological endpoint is based on a dermal toxicity study. As such, a dermal absorption factor is not required and not applied in the risk assessment.

3.5.2 Occupational Exposure and Risk

3.5.2.1 Mixer/loader/applicator Exposure and Risk Assessment

Individuals have potential for exposure to aminocyclopyrachlor during mixing, loading and application. Exposure to workers mixing, loading and applying DPX-MAT 28 Herbicide, Truvist Herbicide, Navius Herbicide or Rejuvra XL Herbicide is expected to be short- to intermediate-term in duration and to occur primarily by the dermal and inhalation routes. Mixer/loader/applicator exposure estimates were derived from applying aminocyclopyrachlor on pasture, rangeland and non-crop areas using groundboom, right-of-way sprayers and handheld equipment, such as manually pressurized handwand, backpack sprayer and mechanically pressurized handgun. The mixer/loader/applicator risk assessments were conducted for the use of DPX-MAT 28 Herbicide, which has the highest application rate on pasture, and Navius Herbicide, which has the highest application rate on rangeland and non-crop areas. The risk

assessments for these two products are adequate to assess the risk from Truvist Herbicide and Rejuvra XL Herbicide, which have lower application rates. The exposure estimates are based on mixer/loader/applicators wearing a long-sleeved shirt, long pants, and chemical-resistant gloves (gloves not required for groundboom application).

As chemical-specific data for assessing human exposures were not submitted, dermal and inhalation exposures for workers were estimated using the Pesticide Handlers Exposure Database (PHED) Version 1.1. PHED is a compilation of generic mixer/loader and applicator passive dosimetry data with associated software which facilitates the generation of scenario-specific exposure estimates.

For the mixer/loader/applicator risk assessment, exposure was estimated by coupling the dermal unit exposure values with the amount of product handled per day. Inhalation exposure was estimated by coupling the inhalation unit exposure values with the amount of product handled per day with 100% inhalation absorption. Exposure was normalized to mg/kg bw/day by using 70 kg adult body weight.

Exposure estimates were compared to the toxicological endpoints (no observed adverse effect levels [NOAELs]) to obtain the MOE; the target MOE is 100. Table 3.5.2.1.1 presents the PHED unit exposure values used. Tables 3.5.2.1.2 and 3.5.2.1.3 present the estimates of exposure and risk for DPX-MAT 28 Herbicide and Navius Herbicide, respectively. Calculated MOEs are above the target MOE of 100. Therefore, risks are not of concern, provided that workers wear the personal protective equipment stated on the product labels.

Table 3.5.2.1.1 PHED unit exposure estimates for mixer/loader and applicator while handling DPX-MAT 28 Herbicide and Navius Herbicide

Exposure scenario		PHED unit exposures (µg/kg a.i. handled)	
		Dermal	Inhalation
A	Dry flowable, open mix/load (single layer + chemical-resistant gloves)	163.77	1.02
B	Open cab groundboom application (single layer)	32.49	0.96
C	Right-of-way sprayer application (single layer + chemical-resistant gloves)	872.54	5.00
D	MLA Liquid backpack (single layer + chemical-resistant gloves)	5445.85	62.1
E	MLA Liquid low pressure handwand (single layer + chemical-resistant gloves)	943.37	45.2
F	MLA Liquid high pressure handwand (single layer + chemical-resistant gloves)	5585.49	151
G	Aerial application	9.66	0.07
Mixer/loader/applicator (MLA) unit exposure values for single layer and chemical-resistant gloves			
A+B	MLA Open mix/load + groundboom application	196.26	1.98
A+C	MLA Open mix/load + right-of-way sprayer application	1036.31	6.02
A+D	MLA Open mix/load + backpack application	5609.62	63.12
A+E	MLA Open mix/load + manually pressurized handwand application†	1107.14	46.22
A+F	MLA Open mix/load + mechanically pressurized handwand application†	5749.26	152.02

MLA = mixer/loader/applicator

† For backpack, low pressure handwand and high pressure handwand applications, only MLA unit exposure values for liquid formulations are available in PHED. As such, to calculate MLA unit exposure for soluble or wettable granules for these application equipment, the dry flowable open mix/load unit exposure is added to the liquid MLA unit exposure.

Table 3.5.2.1.2 Chemical Handler Risk Assessment for DPX-MAT 28 Herbicide for Workers Wearing a Single Layer and Chemical-Resistant Gloves (Gloves Not Required For Groundboom Application)

Exposure scenario		PHED unit exposure (µg/kg a.i. handled)[1]		Rate[2]	ATPD[3]	Exposure (mg/kg bw/day)[4]		Calculated MOEs[5]	
		Dermal	Inhalation			Dermal	Inhalation	Dermal	Inhalation
A+B	MLA Groundboom	196.26	1.98	0.07 kg a.i./ha	360 ha/day	7.07E-02	7.13E-04	14200	153000
A+C	MLA Right-of-way sprayer	1036.31	6.02	0.00035 kg a.i./L	3800 L/day	1.97E-02	1.14E-04	50800	953000
A+D	MLA Backpack sprayer	5609.62	63.12	0.00035 kg a.i./L	150 L/day	4.21E-03	4.73E-05	238000	2300000
A+E	MLA Manually pressurized handwand	1107.14	46.22	0.00035 kg a.i./L	150 L/day	8.30E-04	3.47E-05	1200000	3140000
A+F	MLA Mechanically pressurized handgun	5749.26	152.02	0.00035 kg a.i./L	3800 L/day	1.09E-01	2.89E-03	9150	37700
A	ML for aerial application	163.77	1.02	0.07 kg a.i./ha	400 ha/day	6.55E-02	4.08E-04	15300	267000
G	A for aerial application	9.66	0.07	0.07 kg a.i./ha	400 ha/day	3.86E-03	2.80E-05	259000	3890000

MLA = mixing/loading and applying, ML = mixing/loading, A = applying

[1] PHED unit exposures from Table 3.5.2.1.1

[2] For the rate to be expressed as kg a.i./L for right-of-way sprayers and handheld equipment, the application rate (0.07 kg a.i./ha) was divided by the minimum water volume (200 L/ha)

[3] Default Area Treated per day (ATPD) values

[4] Daily exposure = (PHED unit exposure × ATPD × Rate) / (70 kg bw × 1000 µg/mg)

[5] Dermal MOE is based on NOAEL = 1000 mg/kg bw/day

Inhalation MOE is based on NOAEL = 109 mg/kg bw/day; target MOE = 100 for both routes of exposure

Table 3.5.2.1.3 Chemical Handler Risk Assessment for Navius Herbicide for Workers Wearing a Single Layer and Chemical-Resistant Gloves (Gloves Not Required For Groundboom Application)

Exposure scenario		PHED unit exposure (µg/kg a.i. handled)[1]		Rate[2]	ATPD[3]	Exposure (mg/kg bw/day)[4]		Calculated MOEs[5]	
		Dermal	Inhalation			Dermal	Inhalation	Dermal	Inhalation
A+B	MLA Groundboom	196.26	1.98	0.264 kg a.i./ha	360 ha/day	2.66E-01	2.69E-03	3750	40500
A+C	MLA Right-of-way sprayer	1036.31	6.02	0.000264 kg a.i./L	3800 L/day	1.49E-02	8.63E-05	67300	1260000
A+D	MLA Backpack sprayer	5609.62	63.12	0.000528 kg a.i./L	150 L/day	6.35E-03	7.14E-05	158000	1530000
A+E	MLA Manually pressurized handwand	1107.14	46.22	0.000528 kg a.i./L	150 L/day	1.25E-03	5.23E-05	798000	2080000
A+F	MLA Mechanically pressurized handgun	5749.26	152.02	0.000264 kg a.i./L	3800 L/day	8.24E-02	2.18E-03	12100	50000
A	ML for aerial application	163.77	1.02	0.264 kg a.i./ha	400 ha/day	2.47E-01	1.54E-03	4050	70800
G	A for aerial application	9.66	0.07	0.264 kg a.i./ha	400 ha/day	1.46E-02	1.06E-04	68600	1030000

MLA = mixing/loading and applying, ML = mixing/loading, A = applying

[1] PHED unit exposures from Table 3.5.2.1.1

[2] For the rate to be expressed as kg a.i./L for right-of-way sprayers and high pressure handwand, the application rate (0.264 kg a.i./ha) was divided by the minimum water volume for high volume ground equipment (1000 L/ha).
For the rate to be expressed as kg ai/L for backpack sprayers and low pressure handwand, the application rate (0.264 kg a.i./ha) was divided by the minimum water volume for low volume ground equipment (500 L/ha).

[3] Default Area Treated per day (ATPD) values

[4] Daily exposure = (PHED unit exposure × ATPD × Rate) / (70 kg bw × 1000 µg/mg)

[5] Dermal MOE is based on NOAEL = 1000 mg/kg bw/day
Inhalation MOE is based on NOAEL = 109 mg/kg bw/day; target MOE = 100 for both routes of exposure

3.5.2.2 Exposure and Risk Assessment for Workers Entering Treated Areas

There is potential for exposure to workers re-entering areas treated with DPX-MAT 28 Herbicide, Truvist Herbicide, Navius Herbicide or Rejuvra XL Herbicide during scouting, mechanical weeding and mowing. The duration of exposure is considered to be short- to intermediate-term for all re-entry activities. The primary route of exposure for workers re-entering treated areas would be through the dermal route. Inhalation exposure is not considered to be a significant route of exposure for people entering treated areas compared to the dermal route, since aminocyclopyrachlor is relatively non-volatile (6.92×10^{-6} Pa) and as such, an inhalation risk assessment was not required.

Similar to the mixer/loader/applicator risk assessments, the postapplication risk assessments were conducted for the use of DPX-MAT 28 Herbicide, which has the highest application rate on pasture, and Navius Herbicide, which has the highest application rate on rangeland and non-crop areas. The risk assessments for these two products are adequate to assess the risk from Truvist Herbicide and Rejuvra XL Herbicide, which have lower application rates.

Dermal exposure to workers entering treated areas is estimated by coupling dislodgeable foliar residue values with activity-specific transfer coefficients. Chemical-specific dislodgeable foliar residue data were not submitted. As such, a default dislodgeable foliar residue value (DFR) of 25% of the application rate was used in the exposure assessment to assess postapplication risk on the day of application.

The exposure estimate was compared to the toxicological endpoint (NOAEL = 1000 mg/kg bw/day) to obtain the MOE; the target MOE is 100. Since this value exceeds the target MOE of 100 (Table 3.5.2.2.1), this level of postapplication exposure is not a health concern. A restricted entry interval (REI) of 12 hours for agricultural uses and "until residues are dried" for non-crop uses is adequate.

Table 3.5.2.2.1 Postapplication Exposure Risk Estimates on the Day of Application for Pasture, Rangeland, and Non-Crop Areas Treated with DPX-MAT-28 Herbicide and Navius Herbicide

Exposure scenario	Rate ($\mu g/cm^2$)	Peak DFR ($\mu g/cm^2$)[1]	TC (cm^2/hr)[2]	ED (hr/day)[3]	Exposure (mg/kg bw/day)[4]	MOE[5]
DPX-MAT 28 Herbicide						
Pasture and rangeland: scouting	0.70	0.175	1100	8	0.0220	45500
Non-crop areas: scouting, mechanical weeding and mowing	0.70	0.175	580	8	0.0116	86207
Navius Herbicide						
Rangeland: scouting	2.64	0.66	1100	8	0.0830	12100
Non-crop areas: scouting, mechanical weeding and mowing	2.64	0.66	580	8	0.0437	22900

[1] Calculated based on the default DFR of 25% of the application rate dislodgeable on the day of application
[2] TC = Transfer coefficients from studies from the Agricultural Re-entry Task Force (ARTF)
[3] ED = Exposure duration
[4] Exposure = (Peak DFR × TC × ED)/(70 kg bw × 1000 µg/mg)
[5] Based on NOAEL= 1000 mg/kg bw/day, target MOE = 100

3.5.3 Residential Exposure and Risk Assessment

There are no residential uses for DPX-MAT 28 Herbicide, Truvist Herbicide, Navius Herbicide or Rejuvra XL Herbicide and as such, a residential risk assessment was not required.

3.5.3.1 Bystander Exposure and Risk

Bystander exposure is considered negligible, since the potential for drift is expected to be minimal. Application is limited to only when there is low risk of drift to areas of human habitation or activity, such as houses, cottages, schools and recreational areas, taking into consideration wind speed, wind direction, temperature inversions, application equipment and sprayer settings.

3.6 Food Residues Exposure Assessment

3.6.1 Residues in Plant and Animal Foodstuffs

The residue definition for livestock dietary burden calculation in grass commodities is aminocyclopyrachlor (acid) and aminocyclopyrachlor methyl ester (calculated as the stoichiometric equivalent of aminocyclopyrachlor). The residue definition for risk assessment and enforcement in animal commodities is aminocyclopyrachlor (acid) (calculated in terms of aminocyclopyrachlor equivalents). The data gathering/enforcement analytical method is valid for the quantitation of aminocyclopyrachlor (acid) and aminocyclopyrachlor methyl ester residues in grass and livestock matrices. The residues of aminocyclopyrachlor and aminocyclopyrachlor methyl ester are stable in grass matrices when stored in a freezer at –20°C for 499–502 days. The residues of aminocyclopyrachlor and aminocyclopyrachlor methyl ester are stable in milk, eggs, and bovine muscle and fat when stored in freezer at –20°C for up to 5 months and residues of aminocyclopyrachlor are stable in liver and kidney for up to 5 and 3 months, respectively. Both analytes were found to be stable in extracts of liver and kidney stored frozen for up to 14 days. There are no processed commodities associated with grass. An adequate feeding study in dairy cow was carried out to assess the anticipated residues in livestock matrices resulting from the current uses. Supervised residue trials conducted throughout the Canada and the United States using end-use products containing aminocyclopyrachlor methyl ester at the label rates in or on grass are sufficient to estimate livestock dietary burdens. Grass forage, hay and silage are animal feed items. Based on animal feeding studies and the estimated dietary burdens, MRLs in animal commodities are recommended to cover the secondary residues in livestock matrices.

3.6.2 Dietary Risk Assessment

Chronic dietary risk assessments were conducted using the Dietary Exposure Evaluation Model (DEEM–FCID™, Version 2.14), which uses updated food consumption data from the United States Department of Agriculture's Continuing Surveys of Food Intakes by Individuals, 1994–1996 and 1998.

3.6.2.1 Chronic Dietary Exposure Results and Characterization

The following criteria were applied to the basic chronic analysis: proposed Canadian MRLs for animal commodities and the default processing factor for dried beef. The basic chronic dietary exposure from all supported aminocyclopyrachlor food uses (alone) for the total population, including infants and children, and all representative population subgroups is 0 % of the ADI. Aggregate exposure from food and drinking water is considered acceptable. The PMRA

estimates that chronic dietary exposure to aminocyclopyrachlor from food and drinking water is 0.1 % (0.001 mg/kg bw/day) of the ADI for the total population. The highest exposure and risk estimate is for all infants (< 1 year) at 0.4 % (0.004 mg/kg bw/day) of the ADI.

3.6.2.2 Acute Dietary Exposure Results and Characterization

No appropriate endpoint attributable to a single dose for the general population (including children and infants) was identified.

3.6.3 Aggregate Exposure and Risk

The aggregate risk for aminocyclopyrachlor consists of exposure from food and drinking water sources only; there are no residential uses.

3.6.4 Maximum Residue Limits

Table 3.6.4.1 Proposed Maximum Residue Limits

Commodity	Recommended MRL (ppm)
Meat byproducts of cattle, goats, horses and sheep	0.3
Fat of cattle, goats, horses and sheep	0.05
Meat of cattle, goat, horses and sheep; milk	0.01

For additional information on MRLs in terms of the international situation and trade implications, refer to Appendix II.

The nature of the residues in animal and plant matrices, analytical methodology, field trial data, and the chronic dietary risk estimates are summarized in Appendix I, Tables 1, 5 and 6.

4.0 Impact on the Environment

4.1 Fate and Behaviour in the Environment

Based on physico-chemical properties, aminocyclopyrachlor is soluble in water, is not likely to volatilize from moist soil or water surfaces under field conditions, and is not expected to bioaccumulate.

In the terrestrial environment, aminocyclopyrachlor is moderately persistent to persistent under aerobic conditions and persistent under anaerobic conditions. No major transformation products were identified in the laboratory studies, nor in the field dissipation studies. A minimum amount of CO_2 formation was observed in the laboratory studies with one exception, suggesting that there may be a potential for mineralization. No significant carry-over of aminocyclopyrachlor to the following growing season is expected. Chemical processes including volatilization,

phototransformation and hydrolysis are not expected to contribute to overall dissipation of aminocyclopyrachlor.

Aminocyclopyrachlor sorbs weakly to soil constituents. It is highly mobile and has the potential to leach to groundwater. This is supported by results of laboratory studies, terrestrial field dissipation studies and water modelling.

In the aquatic environment, aminocyclopyrachlor is expected to remain primarily in the water phase. It is stable to hydrolysis and persistent to biotransformation. However, it can be phototransformed in water to as many as five identified major transformation products. The fate and ecotoxicity of the phototransformation products are unknown; however, formation of these products would be limited to clear shallow waters. The major route of dissipation in the aquatic environment is likely to be dilution through water movement because it is highly soluble and persistent. Phototransformation in the clear shallow warer can also be an important route of dissipation.

A summary of environmental fate data is presented in Appendix I, Table 7.

4.2 Environmental Risk Characterization

The environmental risk assessment integrates the environmental exposure and ecotoxicology information to estimate the potential for adverse effects on non-target species. This integration is achieved by comparing exposure concentrations with concentrations at which adverse effects occur. Expected environmental concentrations (EECs) are concentrations of pesticide in various environmental media, such as food, water, soil and air. The EECs are estimated using standard models which take into consideration the application rate(s), chemical properties and environmental fate properties, including the dissipation of the pesticide between applications. Ecotoxicology information includes acute and chronic toxicity data for various organisms or groups of organisms from both terrestrial and aquatic habitats including invertebrates, vertebrates, and plants. Toxicity endpoints used in risk assessments may be adjusted to account for potential differences in species sensitivity as well as varying protection goals (i.e. protection at the community, population, or individual level).

Initially, a screening level risk assessment is performed to identify pesticides and/or specific uses that do not pose a risk to non-target organisms, and to identify those groups of organisms for which there may be a potential risk. The screening level risk assessment uses simple methods, conservative exposure scenarios (for example, direct application at a maximum cumulative application rate) and sensitive toxicity endpoints. A risk quotient (RQ) is calculated by dividing the exposure estimate by an appropriate toxicity value (RQ = exposure/toxicity), and the RQ is then compared to the level of concern (LOC). If the screening level RQ is below the LOC, the risk is considered negligible and no further risk characterization is necessary. If the screening level RQ is equal to or greater than the LOC, then a refined risk assessment is performed to further characterize the risk. A refined assessment takes into consideration more realistic exposure scenarios (such as drift to non-target habitats) and might consider different toxicity endpoints. Refinements may include further characterization of risk based on exposure modelling, monitoring data, results from field or mesocosm studies, and probabilistic risk

assessment methods. Refinements to the risk assessment may continue until the risk is adequately characterized or no further refinements are possible.

4.2.1 Risks to Terrestrial Organisms

A risk assessment of aminocyclopyrachlor was undertaken for terrestrial organisms based on available toxicity data to earthworms (acute), bees (acute oral and contact exposure), birds (acute oral, dietary and chronic), mammals (acute oral and reproduction) and terrestrial plants (effects on seedling emergence and vegetative vigour). A summary of terrestrial toxicity data for aminocyclopyrachlor is presented in Appendix I, Table 8 and the accompanying risk assessment is in Appendix I, Tables 9, 10 and 11. The screening level EEC estimations were based on direct on-field application at a maximum yearly application rate of 264 g a.i./ha, associated with the use of Navius Herbicide.

Earthworms

Aminocyclopyrachlor was not acutely toxic to earthworms (*Eisenia fetida*), with LC_{50} values above the highest test concentrations (> 1000 mg a.i./kg soil). At an EEC of 0.12 mg a.i./kg soil, RQ is < 0.01, indicating that the LOC was not exceeded for earthworms (Appendix I, Table 9).

Bees (pollinators)

Acute oral and contact exposure to aminocyclopyrachlor did not result in significant mortality or sublethal effects in honey bees. The resulting RQs for both acute contact and oral exposure routes were below the LOC, indicating aminocyclopyrachlor is expected to pose a negligible risk to pollinators (Appendix I, Table 9).

Birds and mammals

From acute oral and dietary exposure, aminocyclopyrachlor was practically non-toxic to northern bobwhite quail (*Coturnix virginianus*) and mallard duck (*Anas platyrhynchus*), with no treatment-related mortalities or clinical effects occurring in either species. During 21-week dietary exposure studies, no treatment-related adverse effects on reproductive parameters or on the parental generations were observed for either northern bobwhite or mallard duck (Appendix I, Table 8). The screening level risk assessment was conducted for direct on-field exposure, the most conservative scenario. No unacceptable risk for acute mortality or reproductive effects from aminocyclopyrachlor exposure is expected for small, medium or large birds (Appendix I, Table 10).

The toxicity of aminocyclopyrachlor to rats was used to determine risk to small terrestrial mammals. Aminocyclopyrachlor has no acute and reproductive toxic effects to rats (Appendix I, Table 8). A screening level risk assessment for small, medium and large sized mammals based on a conservative assumption of vegetation and insect food sources did not identify a concern for acute mortality or reproductive risks for aminocyclopyrachlor exposure in fields (Appendix I, Table 10).

Non-target terrestrial vascular plants

The toxicity of a soluble granule formulation of aminocyclopyrachlor to non-target plants was determined through vegetative vigour and seedling emergence assays using standard crop species. Significant adverse effects (i.e., > 25% effect) were observed in all plant species in the vegetative vigour assays and in some of the plant species in the seedling emergence assays. The program ETX 2.0 was used to generate species sensitivity distributions for vegetative vigour and seedling emergence based on normally distributed toxicity data. The hazardous concentration to 5% of the species (HC_5) was then calculated for both vegetative vigour and seedling emergence from their respective species sensitivity distributions (Appendix I, Table 8). This provides a more scientifically robust endpoint, which uses all of the data. The HC_5 value for vegetative vigour was used to calculate the risk quotient as it is more sensitive than seeding emergence.

A screening level assessment was conducted for DPX-MAT 28 Herbicide (for application as a single active) and Navius Herbicide (for maximum application rate of aminocyclopyrachlor) at the on-field maximum application rates of 70 g a.i./ha and 264 g a.i./ha, respectively. The RQ values show that on-field exposure to DPX-MAT28 Herbicide and Navius Herbicide exceeds the LOC to non-target terrestrial plants (Appendix I, Table 9).

A refined assessment considers off-field exposure from drift according to application methods (Appendix I, Table 11). The off-field RQs for DPX-MAT28 Herbicide and Navius Herbicide both exceed the LOC. No-spray buffer zones are required for uses of aminocyclopyrachlor, to mitigate potential effects of spray drift to non-target terrestrial plants.

In addition, the phytotoxicity of aminocyclopyrachlor was compared with the two active ingredients, chlorsulfuron and metsulfuron-methyl, which are co-formulated in the end-use products of Truvist Herbicide and Navius Herbicide and Rejuvra XL Herbicide respectively. The toxicity of these two active ingredients has previously been assessed and is presented in Re-evaluation Decision RVD-2008-08, *Chlorsulfuron* and Re-evaluation Decision RVD2008-35, *Metsulfuron-methyl*, respectively. For chlorsulfuron, the EC_{25} is 0.011 g a.i./ha and for metsulfuron-methyl, the EC_{25} is 0.02 g a.i./ha. Appendix I, Table 11 shows that at the application rates specified on the proposed labels, the RQs for both chlorsulfuron and metsulfuron-methyl are greater than those for aminocyclopyrachlor. Therefore, no-spray buffer zones for uses of Truvist Herbicide, Navius Herbicide and Rejuvra XL Herbicide will be established based on the endpoints of chlorsulfuron or metsulfuron-methyl.

4.2.2 Risks to Aquatic Organisms

Aquatic organisms can be exposed to aminocyclopyrachlor as a result of spray drift and over-land runoff. To assess the potential for adverse effects, screening level EECs in the aquatic environment based on a direct application to water following application to rangeland and non-crop areas were used as the exposure estimates. A risk assessment of aminocyclopyrachlor was undertaken for freshwater and marine aquatic organisms based on available toxicity data to algae (acute), aquatic plants (acute), invertebrates (acute and chronic), fish (acute and chronic) and amphibians (using fish as surrogate). A summary of aquatic toxicity data for aminocyclopyrachlor is presented in Appendix I, Table 8. For acute toxicity studies uncertainty

factors of 1/2 and 1/10 $EC(LC)_{50}$ are used in modifying the toxicity values for aquatic plants and invertebrates, and fish species, respectively, when calculating RQs. No uncertainty factors are applied to chronic NOEC endpoints. The calculated screening level RQs are summarized in Appendix I, Table 8.

Freshwater algae and plants

Of the three algal species tested, aminocyclopyrachlor showed toxic effects on biomass and yield to green-blue alga (*Anaebena flos-aquae*) and diatoms (*Navicula pelliculosa*). For the plant species tested, aminocyclopyrachlor showed toxic effects on growth rate to duckweed (*Lemna gibba G3*) (Appendix I, Table 8). Screening level risk to these organisms did not exceed the LOC (RQ < 0.01; Appendix I, Table 12), indicating aminocyclopyrachlor is expected to pose a negligible risk to freshwater algae and plants.

Freshwater invertebrates

Acute exposure of *Daphnia magna* to aminocyclopyrachlor showed slight toxicity (Appendix I, Table 8). However, chronic exposure to aminocyclopyrachlor did not affect reproduction or show any observable treatment-related effects (Appendix I, Table 8). Screening level RQs for aminocyclopyrachlor did not exceed the LOC for exposure to *Daphnia magna* (Appendix I, Table 12).

Freshwater fish and amphibians

The toxicity of aminocyclopyrachlor to two species of fish was assessed for acute exposure (rainbow trout and bluegill sunfish) and one species for chronic exposure (rainbow trout). Aminocyclopyrachlor was neither acutely toxic nor chronically toxic to fish up to highest test concentration (i.e., LC_{50}s > highest concentration) (Appendix I, Table 8). The screening level risk to fish from aminocyclopyrachlor did not exceed the LOC (Appendix I, Table 12), therefore, negligible risk to freshwater fish is expected.

The risk to amphibians was estimated by comparing EECs in 15 cm water depth with surrogate fish toxicity endpoints (Appendix I, Table 8). Screening level acute and chronic RQs for amphibians did not exceed the LOC (Appendix I, Table 12).

Marine species

Aminocyclopyrachlor was not acutely toxic to Eastern oyster (*Crassostrea virginica*), mysid shrimp (*Americamysis bahia*), sheepshead minnow (*Cyprinidon variegates*) and saltwater diatom (*Skeletonema costatum*). All LC_{50}/EC_{50} values were above the highest test concentrations (Appendix I, Table 8). A screening level risk did not exceed the LOC (Appendix I, Table 12). Therefore, aminocyclopyrachlor is not expected to pose a risk to marine organisms.

4.2.3 Incident Reports

No incident report was found in the United States Environmental Protection Agency EIIS v.2 (Environmental Incident Information System) database, last updated on 6 June 2012.

There were, however, thousands of incidents of toxic effects on trees linked to the use of DuPont Imprelis Herbicide (United States Environmental Protection Agency Registration Number 352-73), a product containing aminocyclopyrachlor acid in the United States. These incidents were related to turf uses only. In Canada, turf use is not included in this application. To address incidents with trees, DuPont conducted several tree studies which were submitted to the United States Environmental Protection Agency and will be required as a condition of full registration in Canada.

5.0 Value

5.1 Effectiveness Against Pests

5.1.1 Acceptable Efficacy Claims for DPX-MAT 28 Herbicide

Data were submitted from small-scale efficacy trials conducted over an eight year period (2004–2011) in Canada and the United States to support the registration of DPX-MAT 28 Herbicide. Treatments were specific to trial, and included one or more of the following:

- one or more rates of DPX-MAT 28 Herbicide (aminocyclopyrachlor present as the acid); and/or,
- an alternate formulation, DPX-KJM 44, containing aminocyclopyrachlor, present as the methyl ester.

Usually a surfactant was included with each of the treatments above, but the surfactant or class of surfactants included was specific to trial. Non-ionic surfactants and Merge Adjuvant were among the surfactants included with the above treatments. In some trials, the efficacy of treatments of Rejuvra XL Herbicide, equivalent to DPX-MAT 28 Herbicide plus a 60% metsulfuron-methyl product, applied with a crop oil concentrate was directly compared to the same treatment applied with Merge Adjuvant.

Many of the field trials conducted in 2007 or later included treatments DPX-MAT 28 Herbicide. Most efficacy trials were replicated and included treatments that were arranged in randomized complete blocks with usually three or four replicates per treatment. Data from field trials conducted in the United States in ecoregions that also occur in Canada, or that are sufficiently similar to an ecoregion that occurs in Canada were considered as core information.

Acceptable efficacy claims for DPX-MAT 28 Herbicide can be found under Appendix I, Tables 13a and 13b.

5.1.2 Acceptable Efficacy Claims for Truvist Herbicide

Data were submitted from small-scale efficacy trials conducted over a 30 year period (1982–2011) in Canada and the United States to support the registration of Truvist Herbicide. Treatments were specific to trial, and included one or more of the following:

- one or more rates of DPX-MAT 28 Herbicide (aminocyclopyrachlor present as the acid) and/or an alternate formulation, DPX-KJM 44, containing aminocyclopyrachlor, present as the methyl ester; and/or,
- one or more rates of a chlorsulfuron herbicide, containing 75% chlorsulfuron, for example, Glean Herbicide Dry Flowable (PCP Registration Number 17245) or Telar Herbicide Toss-N-Go Bags (Registration Number 21533), applied as the lone herbicide; and/or,
- mixtures of aminocyclopyrachlor plus chlorsulfuron at one or more rates, including mixtures of DPX-MAT 28 Herbicide plus Glean Herbicide Dry Flowable at the rate equivalent to that for Truvist Herbicide.

Usually an adjuvant was included with each of the treatments above, but the adjuvant or class of adjuvant included was specific to trial. Non-ionic surfactants, crop oil concentrates and Merge Adjuvant were among the adjuvants used.

Many of the field trials conducted in 2008 or later included treatments of Truvist Herbicide, as mixtures of DPX-MAT 28 Herbicide plus a 75% chlorsulfuron herbicide product. Most efficacy trials were replicated and included treatments that were arranged in randomized complete blocks with usually three or four replicates per treatment. Data from field trials conducted in the United States in ecoregions that also occur in Canada, or that are sufficiently similar to an ecoregion that occurs in Canada were considered as core information. Efficacy claims for which there were registered precedents (Glean Herbicide Dry Flowable or Telar Herbicide Toss-N-Go Bags applied at up to 30 g a.i./ha) or supported precedents (DPX-MAT 28 Herbicide applied at up to 70 g a.i./ha) were also supported for Truvist Herbicide.

Acceptable efficacy claims for Truvist Herbicide can be found under Appendix I, Tables 14a and 14b.

5.1.3 Acceptable Efficacy Claims for Navius Herbicide

Data were submitted from small-scale field trials conducted over a 28 year period (1984–2011) in Canada and the United States to support the registration of Navius Herbicide. Treatments were specific to trial, and included one or more of the following:

- one or more rates of DPX-MAT 28 Herbicide (aminocyclopyrachlor present as the acid) and/or an alternate formulation, DPX-KJM 44, containing aminocyclopyrachlor, present as the methyl ester; and/or,

- one or more rates of a metsulfuron-methyl herbicide, containing 60% metsulfuron-methyl, for example, DuPont Escort Herbicide 60% Dry Flowable (Registration Number 23005) or Ally Herbicide Dry Flowable 60% (Registration Number 20214)/Ally Herbicide Toss-N-Go 60% Dry Flowable (Registration Number 34388), applied as the lone herbicide; and/or,
- mixtures of aminocyclopyrachlor plus metsulfuron-methyl at one or more rates, including mixtures of DPX-MAT 28 Herbicide plus DuPont Escort Herbicide 60% Dry Flowable at rates equivalent to those for Navius Herbicide.

Usually an adjuvant was included with each of the treatments above, but the adjuvant or class of adjuvant included was specific to trial. Non-ionic surfactants, crop oil concentrates and Merge Adjuvant were among the adjuvants used.

Many of the field trials conducted in 2008 or later included treatments of Navius Herbicide, as mixtures of DPX-MAT 28 Herbicide plus a 60% metsulfuron-methyl herbicide product. Most efficacy trials were replicated and included treatments that were arranged in randomized complete blocks with usually three or four replicates per treatment. Data from field trials conducted in the United States in ecoregions that also occur in Canada, or that are sufficiently similar to an ecoregion that occurs in Canada were considered as core information. Efficacy claims for which there were relevant registered precedents (DuPont Escort Herbicide 60% Dry Flowable or Ally Herbicide Dry Flowable 60% /Ally Herbicide Toss-N-Go 60% Dry Flowable applied at up to 84 g a.i./ha) or relevant supported precedents (DPX-MAT 28 Herbicide applied at up to 70 g a.i./ha, or Rejuvra XL Herbicide applied at either 45 or 90 g a.i./ha) were also supported for Navius Herbicide.

Acceptable efficacy claims for Navius Herbicide can be found under Appendix I, Tables 15a and 15b.

5.1.4 Acceptable Efficacy Claims for Rejuvra XL Herbicide

Data were submitted from small-scale field trials conducted over a 28 year period (1984–2011) in Canada and the United States to support the registration of Rejuvra XL Herbicide. Treatments were specific to trial, and included one or more of the following:

- one or more rates of DPX-MAT 28 Herbicide (aminocyclopyrachlor present as the acid) and/or an alternate formulation, DPX-KJM 44, containing aminocyclopyrachlor, present as the methyl ester; and/or,
- one or more rates of metsulfuron-methyl herbicide, containing 60% metsulfuron-methyl, for example, DuPont Escort Herbicide 60% Dry Flowable or Ally Herbicide Dry Flowable 60% /Ally Herbicide Toss-N-Go 60% Dry Flowable, applied as the lone herbicide; and/or,
- mixtures of aminocyclopyrachlor plus metsulfuron-methyl at one or more rates, including mixtures of DPX-MAT 28 Herbicide plus DuPont Escort Herbicide 60% Dry Flowable at rates equivalent to those for Rejuvra XL Herbicide.

Usually an adjuvant was included with each of the treatments above, but the adjuvant or class of adjuvant included was specific to trial. Non-ionic surfactants, crop oil concentrates and Merge Adjuvant were among the adjuvants used.

Many of the field trials conducted in 2008 or later included treatments of Rejuvra XL Herbicide, as mixtures of DPX-MAT 28 Herbicide plus a 60% metsulfuron-methyl herbicide product. Most efficacy trials were replicated and included treatments that were arranged in randomized complete blocks with usually three or four replicates per treatment. Data from field trials conducted in the United States in ecoregions that also occur in Canada, or that are sufficiently similar to an ecoregion that occurs in Canada were considered as core information. Efficacy claims for which there were registered relevant precedents (DuPont Escort Herbicide 60% Dry Flowable or Ally Herbicide Dry Flowable 60% /Ally Herbicide Toss-N-Go 60% Dry Flowable) applied at up to 18 g a.i./ha) or relevant supported precedents (DPX-MAT 28 Herbicide applied at up to 35 g a.i./ha) were also supported for Rejuvra XL Herbicide.

Acceptable efficacy claims for Rejuvra XL Herbicide can be found under Appendix I, Tables 16a and 16b.

5.2 Non-Safety Adverse Effects

Pastures, rangelands, and some non-crop areas, such as roadsides, typically include an array of naturally established or planted grasses. Aminocyclopyrachlor, like most other synthetic auxin type herbicides, are much more herbicidally active on broadleaved plants than on graminaceous plants, which is the basis for the selectivity of these herbicides. The tolerance of grasses to aminocyclopyrachlor, as either DPX-MAT 28 Herbicide or the methyl ester formulation (DPX-KJM 44), was assessed in several trials. Generally, grasses exhibited adequate tolerance to aminocyclopyrachlor applied at 70 g a.e./ha. Metsulfuron-methyl, such as DuPont Escort Herbicide 60% Dry Flowable, containing 60% metsulfuron-methyl, is registered for use on rangeland and non-crop areas, such as roadsides, at up to 90 g a.i./ha, and pastures at up to 18 g a.i./ha. Furthermore, data generated for separate treatments of tank mixtures of aminocyclopyrachlor plus metsulfuron-methyl applied at rates relevant to those proposed for Rejuvra XL Herbicide or the lowest rate of Navius Herbicide demonstrated that grasses were generally tolerant of these treatments. A further consideration is that removal of competition from broadleaved weeds may facilitate recovery of grasses that may be injured by these treatments. Tolerance of grasses to tank mixtures of aminocyclopyrachlor plus metsulfuron-methyl at rates relevant to higher rates of Navius Herbicide was more variable; however; these higher rates would likely be used for spot treatment of woody plant species rather than as a broadcast treatment. The applicant has included a statement to advise of the possibility of injury to grasses on the labels of DPX-MAT 28 Herbicide, Navius Herbicide, Truvist Herbicide and Rejuvra XL Herbicide. As DPX-MAT 28 Herbicide and Rejuvra XL Herbicide are intended for the control or suppression of broadleaved weeds and may be used in pastures, the applicant has included a labeling statement to advise that severe injury may occur to desirable broadleaved species, such as alfalfa and red clover. As Truvist Herbicide may only be used in non-crop areas, an assessment of the tolerance of grasses was not required.

5.3 Tolerance of Crops Grown in Rotation

As rangelands are not cropped and as pastures are normally maintained over many years and are rarely followed by other crops, there was no requirement for a rotational crop tolerance assessment.

5.4 Economics

No market analysis was done for this application.

5.5 Sustainability

5.5.1 Survey of Alternatives

Several herbicides are available for use in pastures, rangeland, and/or non-crop areas for the postemergence control of broadleaved weeds and woody plant species. These include products having modes of action from the following modes of action groups as per the WSSA classification:

- for grass pasture: Groups 2, 4 and 11
- for rangeland: Groups 2 and 4
- for non-crop areas: Groups 2, 4, 5, 7, 9, 11 and 22.

5.5.2 Compatibility with Current Management Practices Including Integrated Pest Management

DPX-MAT 28 Herbicide provides an additional Group 4 herbicide option for the control or suppression of broadleaved weeds and some woody plant species in pasture, rangeland and non-crop areas. The co-formulated products, Rejuvra XL Herbicide, Navius Herbicide and Truvist Herbicide, provide additional options to other herbicide products containing both Group 2 and Group 4 active ingredients and that are registered for the same use sites. As these four products are applied to emerged weeds and woody plant species, the suitability of these herbicides in combatting the particular weeds present can be assessed prior to application. The use of these herbicides does not restrict the sequential use of other herbicides of alternate modes of action that are registered for the same use sites.

5.5.3 Information on the Occurrence or Possible Occurrence of the Development of Resistance

Repeated use of herbicides having the same mode of action in a weed control program increases the probability of selecting naturally resistant biotypes. As aminocyclopyrachlor is a Group 4 herbicide that belongs to a new chemical family, it may contribute to the management of broadleaved weeds that are not cross-resistant to other Group 4 herbicides as well as contributing to resistance management in the same manner as other Group 4 herbicides. As Rejuvra XL Herbicide, Navius Herbicide and Truvist Herbicide each contain a sulfonylurea (Group 2) herbicide, these herbicides may reduce the potential for the development of resistance to Group 2 herbicides, since aminocyclopyrachlor has herbicidal activity on many of the same weeds that are normally susceptible to metsulfuron-methyl or chlorsulfuron.

Herbicide products containing aminocyclopyrachlor should be used in rotation with other selective herbicides having different modes of action for the control or suppression of emerged broadleaved weeds. While the options for rotating with selective herbicides of other modes of action are limited for pastures and rangeland, there are more such options for non-crops areas.

DPX-MAT 28 Herbicide, Rejuvra XL Herbicide, Navius Herbicide and Truvist Herbicide are alternative herbicides belonging to Group 2 (with respect to DPX-MAT 28 Herbicide only), 5, 7, 9, 11 and 22 chemistries for the control or suppression of emerged broadleaved weed and undesirable brush in one or more of pastures, rangeland and non-crop areas. Herbicide-resistant populations of several broadleaved weed species have been discovered and are variously resistant to herbicides, including those that belong to WSSA Group 2 (acetolactate synthase inhibitors), Group 4 (synthetic auxins), Group 5 (inhibitors of photosynthesis at photosystem II), Group 7 (inhibitors of photosynthesis at photosystem II), Group 9 (EPSP synthase inhibitors: glyphosate); and Group 22 (photosystem I electron diversion).

When applied at the labeled use rates, DPX-MAT 28 Herbicide, Rejuvra XL Herbicide, Navius Herbicide and Truvist Herbicide are expected to control or suppress biotypes of labeled weeds that are resistant to other groups of chemistries. Consequently, aminocyclopyrachlor has the potential to delay the onset of herbicide resistance and to combat certain forms of resistance once present. Due to their longer generational times (often many years), resistance to herbicides is less of a concern for woody plant species.

The labels of DPX-MAT 28 Herbicide, Rejuvra XL Herbicide, Navius Herbicide and Truvist Herbicide each include the resistance management statements, as per Regulatory Directive DIR99-06, *Voluntary Pesticide Resistance-Management Labelling Based on Target Site/Mode of Action*.

6.0 Pest Control Product Policy Considerations

6.1 Toxic Substances Management Policy Considerations

The Toxic Substances Management Policy (TSMP) is a federal government policy developed to provide direction on the management of substances of concern that are released into the environment. The TSMP calls for the virtual elimination of Track 1 substances [those that meet all four criteria outlined in the policy, i.e., persistent (in air, soil, water and/or sediment), bio-accumulative, primarily a result of human activity and toxic as defined by the *Canadian Environmental Protection Act*].

During the review process, DPX-MAT28 Herbicide and its transformation products were assessed in accordance with the PMRA Regulatory Directive DIR99-03[5] and evaluated against the Track 1 criteria. The PMRA has reached the following conclusions:

- Aminocyclopyrachlor does not meet all Track 1 criteria, and is not considered a Track 1 substance. See Table 6.1.1 for comparison with Track 1 criteria.
- Aminocyclopyrachlor is unlikely to form any transformation products that meet all Track 1 criteria. See Table 6.1.1 for comparison with Track 1 criteria.

Table 6.1.1 Toxic Substances Management Policy Considerations—Comparison of Aminocyclopyrachlor to TSMP Track 1 Criteria

TSMP Track 1 Criteria	TSMP Track 1 Criterion value		Active Ingredient Endpoints	Transformation Products Endpoints
CEPA toxic or CEPA toxic equivalent[1]	Yes		yes	yes
Predominantly anthropogenic[2]	Yes		Yes	yes
Persistence[3]	Soil	Half-life ≥ 182 days	56.8–435	not available
	Water	Half-life ≥ 182 days	Half-life	not available
	Sediment	Half-life ≥ 365 days	Half-life	not available
	Air	Half-life ≥ 2 days or evidence of long	Volatilisation is not an important route of dissipation and long-range atmospheric	not available

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

		range transport	transport is unlikely to occur based on the vapour pressure ($6.92x10^{-6}$ Pa at 20˚C) and Henry's law constant ($3.47x10^{-12}$ atm m^3 mol^{-1} at pH 7 and 20˚C).	
Bioaccumulation[4]	Log $K_{OW} \geq 5$		–2.48 at 20˚C	< 5
	BCF ≥ 5000		not available	
	BAF ≥ 5000		not available	
Is the chemical a TSMP Track 1 substance (all four criteria must be met)?			No, does not meet TSMP Track 1 criteria.	No, does not meet TSMP Track 1 criteria.

1 All pesticides will be considered CEPA-toxic or CEPA toxic equivalent for the purpose of initially assessing a pesticide against the TSMP criteria. Assessment of the CEPA toxicity criteria may be refined if required (i.e., all other TSMP criteria are met).

2 The policy considers a substance "predominantly anthropogenic" if, based on expert judgement, its concentration in the environment medium is largely due to human activity, rather than to natural sources or releases.

3 If the pesticide and/or the transformation product(s) meet one persistence criterion identified for one media (soil, water, sediment or air) than the criterion for persistence is considered to be met.

4 Field data (for example, BAFs) are preferred over laboratory data (for example, BCFs) which, in turn, are preferred over chemical properties (for example, log K_{ow}).

6.2 Formulants and Contaminants of Health or Environmental Concern

During the review process, contaminants in the technical and formulants and contaminants in the end-use products are compared against the *List of Pest control Product Formulants and Contaminants of Health or Environmental Concern* maintained in the *Canada Gazette*.[6] The list is used as described in the PMRA Notice of Intent NOI2005-01[7] and is based on existing policies and regulations including DIR99-03 and DIR2006-02,[8] and taking into consideration the Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act* (substances designated under the Montreal Protocol). The PMRA has reached the following conclusions:

- Technical grade aminocyclopyrachlor and the end-use product DPX-MAT 28 Herbicide do not contain any formulants or contaminants of health or environmental concern identified in the *Canada Gazette.*

6 *Canada Gazette*, Part II, Volume 139, Number 24, SI/2005-114 (2005-11-30) pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* and in the order amending this list in the *Canada Gazette*, Part II, Volume 142, Number 13, SI/2008-67 (2008-06-25) pages 1611-1613. *Part 1 Formulants of Health or Environmental Concern, Part 2 Formulants of Health or Environmental Concern that are Allergens Known to Cause Anaphylactic-Type Reactions and Part 3 Contaminants of Health or Environmental Concern.*

7 NOI2005-01, *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern under the New Pest Control Products Act*.

8 DIR2006-02, *Formulants Policy and Implementation Guidance Document*.

- A List 2 formulant in aminocyclopyrachlor products was identified as an impurity of concern. Based on the relatively low levels in the proposed formulation, it was not of toxicological or environmental concern. The proposed label recommendations take into account the presence of this formulant component.

7.0 Summary

7.1 Human Health and Safety

The toxicology database submitted for aminocyclopyrachlor is adequate to define the majority of toxic effects that may result from exposure. There was no indication that aminocyclopyrachlor caused damage to the nervous system or immune system. Aminocyclopyrachlor did not cause birth defects in animals and there were no effects on the ability to reproduce. The primary effects following short term and chronic dosing consisted of decreased body weight gain, which was only observed in rats. When aminocyclopyrachlor was given to pregnant or nursing animals, no effects on the developing fetus or juvenile animal were observed. There was no evidence to suggest that aminocyclopyrachlor damaged genetic material. There was equivocal evidence of brain tumours in rats following prolonged exposure at the high dose. The risk assessment protects against the toxic effects noted above by ensuring that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests.

The nature of the residue in grass and ruminants is adequately understood. The residue definition for enforcement of MRLs in animal commodities is aminocyclopyrachlor. The proposed use of aminocyclopyrachlor on pasture and rangeland does not represent a chronic dietary risk of concern (food and drinking water) to any segment of the population, including infants, children, adults and seniors. The PMRA does not establish MRLs on animal feed commodities. Sufficient crop residue data have been reviewed to recommend maximum residue limits to protect human health. The PMRA recommends that the following maximum residue limits be specified for:

Commodity	Recommended MRL (ppm)
Meat byproducts of cattle, goats, horses and sheep	0.3
Fat of cattle, goats, horses and sheep	0.05
Meat of cattle, goat, horses and sheep; milk	0.01

Mixer/loaders and applicators handling DPX-MAT 28 Herbicide, Truvist Herbicide, Navius Herbicide or Rejuvra XL Herbicide and workers re-entering treated pasture, rangeland and non-crop areas are not expected to be exposed to levels of aminocyclopyrachlor that will result in risks of concern when DPX-MAT 28 Herbicide, Truvist Herbicide, Navius Herbicide or Rejuvra XL Herbicide are used according to label directions. The personal protective equipment on the product labels is adequate to protect workers.

7.2 Environmental Risk

Aminocyclopyrachlor is moderately persistent to persistent in the terrestrial environment and persistent in the aquatic environment with the exception of the photic zones where it is not expected to persist. It may potentially be redistributed in to the environment through compost products containing treated plant materials and animal manure. Aminocyclopyrachlor is highly mobile and has the potential to leach to groundwater. Aminocyclopyrachlor can pose a risk to non-target terrestrial plants including coniferous and deciduous trees. Risks can be mitigated with spray buffer zones to protect sensitive terrestrial habitats from spray drift and through the use of label statements to inform users of potential risks to the environment.

7.3 Value

The information submitted to register DPX-MAT 28 Herbicide are adequate to describe its efficacy when applied at 30, 35 or 70 g a.i./ha, and in a manner consistent with its labelling for the control or suppression of an array of emerged broadleaved weeds and select woody plant species in pasture, rangeland and non-crop areas.

The information submitted to register Truvist Herbicide are adequate to describe its efficacy when applied at 92.9 g a.i./ha, and in a manner consistent with its labelling, for the control or suppression of a large spectrum of emerged broadleaved weeds and select woody plant species in non-crop areas.

The information submitted to register Navius Herbicide are adequate to describe its efficacy when applied at 87, 174, 260 or 348 g a.i./ha, and in a manner consistent with its labelling for the control or suppression of a large spectrum of emerged broadleaved weeds and woody plant species in rangeland and non-crop areas.

The information submitted to register Rejuvra XL Herbicide are adequate to describe its efficacy when applied at 45 and 90 g a.i./ha, and in a manner consistent with its labelling, for the control or suppression of a large spectrum of emerged broadleaved weeds and select woody plant species in pasture, rangeland and non-crop areas.

While these herbicides have not been proposed as a replacement for any other herbicide registered for the same use sites, aminocyclopyrachlor belongs to a new chemical family, which may contribute to the management of weeds that are not cross-resistant to other Group 4 herbicides as well as contributing to resistance management in the same manner as other Group 4 herbicides registered for rangeland and non-crop sites. Truvist Herbicide, Rejuvra XL Herbicide and Navius Herbicide may reduce the potential for the development of resistance to Group 2 herbicides since aminocyclopyrachlor has herbicidal activity on many of the same weeds that are normally susceptible to chlorsulfuron, contained in Truvist Herbicide, and metsulfuron-methyl, the Group 2 active ingredient contained in Rejuvra XL Herbicide and Navius Herbicide.

The value of these herbicides essentially relates to the large weed spectrum, particularly for the three coformulated products, as compared to other registered Group 2 and Group 4 herbicides applied alone in pastures, rangeland and/or non-crop areas, and to their potential contribution to resistance management.

8.0 Proposed Regulatory Decision

Health Canada's PMRA, under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of Aminocyclopyrachlor Technical and DPX-MAT 28 Herbicide, Truvist Herbicide, Navius Herbicide and Rejuvra XL Herbicide, containing the technical grade active ingredient aminocyclopyrachlor, to control several broadleaved weeds and woody plant species in pastures, rangelands and various non-crop sites.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

List of Abbreviations

µg	micrograms
AD	administered dose
ADI	acceptable daily intake
a.e.	acid equivalent
a.i.	active ingredient
ALS	acetolactate synthase
AR	applied radioactivity
ARTF	Agricultural Re-entry Task Force
atm	atmosphere
ATPD	area treated per day
BAF	Bioaccumulation factor
BCF	Bioconcentration factor
Bq	Becquerel
bw	body weight
BW	generic body weight
bwg	bodyweight gain
CAF	composite assessment factor
CAS	Chemical Abstracts Service
CEPA	*Canadian Environmental Protection Act*
cm	centimetres
d	day
DACO	data code
DEEM	Dietary Exposure Evaluation Model
DFOP	double first-order in parallel
DFR	dislodgeable foliar residue
dw	dry weight
EC_5	effective concentration on 5% of the population
EC_{25}	effective concentration on 25% of the population
EC_{50}	effective concentration on 50% of the population
ED	exposure duration
EDE	estimated daily exposure
EEC	expected environmental concentration
ER_{25}	effective rate for 25% of the population
F1	first generation
fc	food consumption
fe	food efficiency
FIR	food ingestion rates
g	gram
GC-MS	gas chromatography mass spectroscopy
GIT	gastro intestinal tract
ha	hectare
HAFT	highest average field trial
HC	historical control
HC_5	hazardous concentration to 5% of the species
HDPE	high density polyethylene

HDT	highest dose tested
HPLC-MS/MS	high-performance liquid chromatography with tandem mass spectrometry
h	hour
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram
K_d	soil-water partition coefficient
K_{desorb}	soil desorption coefficient
K_{oc}	organic-carbon partition coefficient
K_{ow}	*n*–octanol-water partition coefficient
L	litre
LC_{50}	lethal concentration 50%
LD_{50}	lethal dose 50%
LLNA	local lymph node assay
LOAEL	lowest observed adverse effect level
LOC	level of concern
LOD	limit of detection
LOQ	limit of quantitation
m	metre
MAS	maximum average score
MBD	more balanced diet
mg	milligram
mL	millilitre
ML	mixer/loader
MLA	mixer/loader/applicator
MOE	margin of exposure
mol	mole
MRL	maximum residue limit
MS	mass spectrometry
mw	molecular weight
m/z	mass-to-charge ratio of an ion
N/A	not applicable
nm	nanometre
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
NZW	New Zealand white
P	parental generation
Pa	pascals
PCPA	*Pest Control Product Act*
PHED	Pesticide Handlers Exposure Database
PHI	preharvest interval
p*K*a	dissociation constant
PMRA	Pest Management Regulatory Agency
ppb	parts per billion
ppm	parts per million
RQ	risk quotient
SD	standard deviation
SFO	single first-order

SG	soluble granule
SL	soluble liquid concentrate
STMdR	supervised trial median residue
STMR	supervised trial mean residue
TC	transfer coefficient
TDAR	T-dependant antigen response
T_{max}	time to peak blood concentration
TRR	total radioactive residue
TSMP	Toxic Substances Management Policy
UV	ultraviolet
v/v	volume per volume dilution
WG	wettable granule
wk	week
WOE	weight-of-evidence
WP	wettable powder
WSSA	Weed Science Society of America
yr	year

Appendix I Tables and Figures

Table 1 Residue Analysis

Matrix	Analyte	Method Type	LOQ		Reference
Plant	Aminocyclopyrachlor, aminocyclopyrachlor methyl ester, IN-LXT69	LC-MS/MS (Method ID DuPont-22582)	0.01 ppm/analyte	Grass forage and hay	PMRA # 1998682, 1998286, 1998287, 1998288
	Aminocyclopyrachlor, aminocyclopyrachlor methyl ester, IN-LXT69, IN-QFH57, IN-QGC48	LC-MS/MS (Method ID DuPont-22582 SU1 RV2)			
Animal	Aminocyclopyrachlor, aminocyclopyrachlor methyl ester, IN-LXT69	LC-MS/MS (Method ID DuPont-25836 for eggs, milk and bovine tissues and DuPont-27162, Revisions no. 1 for milk and bovine tissues)	0.01 ppm/analyte	Eggs, milk, and bovine tissues	PMRA # 1998300
			0.01 ppm/analyte	Milk and bovine tissues	PMRA # 1998689, 1998690
Water	DPX-MAT 28 (active)	LC/MS/MS Mass transitions (m/z): 214.0>68.0, 214.0>101.0	0.10 ppb	Creek water, pond water, tap water and well water	PMRA # 1998688
Water	DPX-KJM44	LC/MS/MS Mass transitions (m/z): 228.0>68.0, 228.0>168.0	0.10 ppb	Creek water, pond water, tap water and well water	
Water	IN-LXT69	LC/MS/MS Mass transitions (m/z):170.0>76.0, 170.0>103.0	0.10 ppb	Creek water, pond water, tap water and well water	
Water	IN-QFH57	LC/MS/MS Mass transitions (m/z): 176.27>131.9, 176.27>105.0	0.10 ppb	Creek water, pond water, tap water and well water	
Water	IN-V0977	GC/MS Monitored ions (m/z): 85.0 (quantitative), 86.0, 181.0 (confirmatory)	0.30 ppb	surface water, well water, tap water	PMRA # 2256194
Water	IN-YY905	HPLC-MS/MS Monitored ions (m/z): Q1 85, 86; Q3 68, 43	0.10 ppb	surface water, well water, tap water	PMRA # 2256194
Water	IN-Q3007	HPLC-MS/MS Monitored ions (m/z): Q1 86, 86; Q3 44, 69	0.20 ppb	surface water, well water, tap water	

Matrix	Analyte	Method Type	LOQ	Reference
Soil	DPX-MAT 28 (active)	LC/MS/MS	1.0 ppb	PMRA # 1998685, 1998686, 1998687
	DPX-KJM44	LC/MS/MS	1.0 ppb	
	IN-LXT69	LC/MS/MS	1.0 ppb	
	IN-QFH57	LC/MS/MS	1.0 ppb	
Sediment	The method for soil is deemed to be extensible for sediment.			

Table 2 Toxicity Profile of End-use Products Containing Aminocyclopyrachlor
(Effects are known or assumed to occur in both sexes unless otherwise noted; in such cases, sex-specific effects are separated by semi-colons.)

Study Type/Animal/PMRA #	Study Results
DPXMAT 28 Herbicide	
Acute Oral, up-down Sprague-Dawley rats PMRA# 1998273	LD_{50} > 5,000 mg/kg bw **Low toxicity**
Acute Dermal Sprague-Dawley rats PMRA# 1998274	LD_{50} > 5,000 mg/kg bw **Low toxicity**
Acute Inhalation (nose-only) Sprague-Dawley rats PMRA# 1998275	LC_{50} > 5.02 mg/L **Low toxicity**
Primary Eye Irritation NZW rabbits PMRA# 1998276	$MAS_{24,\ 48\ \&\ 72\ hrs}$ = 18.1/110 **Mildly irritating**
Primary Dermal Irritation NZW rabbits PMRA# 1998277	$MAS_{24,\ 48\ \&\ 72\ hrs}$ = 0.22/8 **Minimally irritating**
Dermal Sensitization (LLNA*) CBA/JH/sd mice PMRA# 1998278	**Non-Sensitizing**
Truvist Herbide	
Acute Oral, up-down Sprague-Dawley rats PMRA# 1998363	LD_{50} > 5,000 mg/kg bw **Low toxicity**

Study Type/Animal/PMRA #	Study Results
Acute Dermal Sprague-Dawley rats PMRA# 1998359	LD_{50} > 5,000 mg/kg bw **Low toxicity**
Acute Inhalation (nose-only) Sprague-Dawley rats PMRA# 1998367	LC_{50} > 5.11 mg/L **Low toxicity**
Primary Eye Irritation NZW rabbits PMRA# 1998365	$MAS_{24,\ 48\ \&\ 72\ hrs}$ = 3.1/110 **Minimally irritating**
Primary Dermal Irritation NZW rabbits PMRA# 1998366	$MAS_{24,\ 48\ \&\ 72\ hrs}$ = 0.11/8 **Minimally irritating**
Dermal Sensitization (LLNA) CBA/JH/sd mice PMRA# 1998361	**Non-Sensitizing**
Navius Herbicide	
Acute Oral, up-down Sprague-Dawley rats PMRA# 2263975	LD_{50} > 5,000 mg/kg bw **Low toxicity**
Acute Dermal Sprague-Dawley rats PMRA# 2263976	LD_{50} > 5,000 mg/kg bw **Low toxicity**
Acute Inhalation (nose-only) Sprague-Dawley rats PMRA# 2263977	LC_{50} > 5.18 mg/L **Low toxicity**
Primary Eye Irritation NZW rabbits PMRA# 2263979	$MAS_{24,\ 48\ \&\ 72\ hrs}$ = 6/110 **Minimally irritating**
Primary Dermal Irritation NZW rabbits PMRA# 2263978	$MAS_{24,\ 48\ \&\ 72\ hrs}$ = 0.4/8 **Minimally irritating**

Study Type/Animal/PMRA #	Study Results
Dermal Sensitization (LLNA) CBA/JH/sd mice PMRA# 2263980	**Non-Sensitizing**
Rejuvra XL Herbicide	
Acute Oral, up-down Sprague-Dawley rats PMRA# 2263943	LD_{50} > 5,000 mg/kg bw **Low toxicity**
Acute Dermal Sprague-Dawley rats PMRA# 2263944	LD_{50} > 5,000 mg/kg bw **Low toxicity**
Acute Inhalation (nose-only) Sprague-Dawley rats PMRA# 2263945	LC_{50} > 5.13 mg/L **Low toxicity**
Primary Eye Irritation NZW rabbits PMRA# 2263947	$MAS_{24,\ 48\ \&\ 72\ hrs}$ = 3.4/110 **Minimally irritating**
Primary Dermal Irritation NZW rabbits PMRA# 2263946	$MAS_{24,\ 48\ \&\ 72\ hrs}$ = 0/8 **Non-irritating**
Dermal Sensitization (LLNA) CBA/JH/sd mice PMRA# 2263948	**Non-Sensitizing**

* LLNA = local lymph node assay

Table 3 Toxicity Profile of Technical Aminocyclopyrachlor
(Effects are known or assumed to occur in both sexes unless otherwise noted; in such cases, sex-specific effects are separated by semi-colons. Organ weight effects reflect both absolute organ weights and relative organ to bodyweights unless otherwise noted.)

Study Type/Animal/PMRA #	Study Results
Metabolism/Pharmacokinetics Sprague Dawley rats PMRA# 1998679, 1998680	Radiolabelled aminocyclopyrachlor was administered to rats as a single oral dose at 25 or 500 mg/kg bw or as repeated oral doses at 25 mg/kg bw. In addition, male and female bile-cannulated rats were administered a single oral dose of radiolabelled aminocyclopyrachlor at 25 or 500 mg/kg bw. Following administration of a single dose at 25 mg/kg bw, 50–60% of the administered dose (AD) was absorbed compared to 42–46% at 500 mg/kg bw. In plasma and blood, T_{max} occurred within 1 hour in all dose groups, indicating rapid absorption. The half-life in plasma was 6 hours in the low and high dose groups. The ratio of maximum concentration in red blood cell to plasma ranged from 0.33–0.48, indicating a limited potential for uptake and binding in red blood cell. The highest concentrations outside of the GIT and carcass at most time points after dosing were detected in the muscle at 25 and 500 mg/kg bw. At 72 hours, the carcass had the highest measured levels. There was no significant difference between males and females at either dose. Elimination half-lives were typically short for the plasma in the single dose groups (5–6 hours in males and females) with slightly higher concentrations found in the females in each group. In the repeat dose groups, the total recovery was >95% AD. Most of the dose was excreted within the first 24 hours (>80% AD), with excretion being similar in males and females. Excretion occurred primarily through the feces (58–69% AD) with urine around 22–35%. Minor residues were isolated in the cage wash and carcass. There were no radioactive residues in expired air. Males excreted slightly more radiolabel in the urine at low dose than the females. Excretion was similar between sexes at the high dose. Minimal amounts of the absorbed dose were found in the bile (<1% AD) at 25 and 500 mg/kg bw. No significant differences were observed in toxicokinetic profiles based on sex or dose. DPX-MAT 28 Herbicide was excreted unchanged.
Acute Oral, up-down Sprague-Dawley rats PMRA# 1998609	LD_{50} > 5,000 mg/kg bw ♀ **Low toxicity**
Acute Dermal Sprague-Dawley rats PMRA# 2263944	LD_{50} > 5,000 mg/kg bw **Low toxicity**
Acute Inhalation (nose-only) Sprague-Dawley rats PMRA# 1998610	LC_{50} > 5.4 mg/L **Low toxicity**

Study Type/Animal/PMRA #	Study Results
Primary Eye Irritation NZW rabbits PMRA# 1998611	$MAS_{24, 48 \& 72 hrs}$ = 2.9/110 **Minimally irritating**
Primary Dermal Irritation NZW rabbits PMRA# 1998613	$MAS_{24, 48 \& 72 hrs}$ = 0.08/8 **Slightly irritating**
Dermal Sensitization (LLNA) CBA/JH/sd mice PMRA# 2263948	**Non-Sensitizing**
28-Day Dermal PMRA 1998629 Sprague-Dawley rats	NOAEL: 1000 mg/kg bw/day LOAEL: not determined Slight dermal irritation was observed in 1 ♂ at 400 mg/kg bw/day and in 2 ♀ at 1000 mg/kg bw/day There were no treatment-related systemic effects.
90-day, oral (diet) PMRA 1998615 Crlj: CD1 (ICR) mice	NOAEL: ♂ = 1088 ♀ = 1623 mg/kg bw/day LOAEL: not determined
90-day, oral (diet) PMRA 1998618 Sprague Dawley rats	NOAEL(HDT): ♂ = 349 ♀ = 448 mg/kg bw/day LOAEL: ♂ = 1045 ♀ = 1425 mg/kg bw/day **1044.6/1424.9 mg/kg bw/day (♂/♀):** ↓ bw, bwg, fc and fe FOB conducted – no effects
90-day, oral (diet) PMRA 1998624 Beagle dogs	NOAEL: ♂ = 426, ♀ = 388 mg/kg bw/day LOAEL: not determined No adverse effects at any dose.
1-year, oral (diet) PMRA 1998659 Beagle dogs	NOAEL: ♂ = 1077, ♀ = 1073 mg/kg bw/day LOAEL: not determined No treatment-related effects at any dose.
18-month Oncogenicity, oral (diet) PMRA 1998634 Crlj: CD1 (ICR) mice	NOAEL: ♂ = 876 ♀ = 1190 mg/kg bw/day LOAEL: not determined No treatment-related effects at any dose.

Study Type/Animal/PMRA #	Study Results
24-Month Chronic/Oncogenicity, oral (diet) PMRA 1998644 Sprague-Dawley rats	NOAEL: ♂ = 279, ♀ = 309 mg/kg bw/day LOAEL: ♂ = 892, ♀ = 957 mg/kg bw/day **892/957 mg/kg bw/day (♂/♀):** ↓ bw, bwg and fe Neoplastic Lesions: **892 mg/kg bw/day (♂):** brain tumours (astrocytomas incidence: 0, 0, 0, 1, 4.3%; HC: 4.29%; glioma incidence: 0, 0, 0, 0, 1%; HC: 1.92%; oligodendroglioma incidence: 0, 0, 0, 1, 0%; HC: 2%; combined incidence 0, 0, 0, 3, 5%) **Equivocal evidence of carcinogenicity**
Reproductive, oral (diet) PMRA# 1998662 Sprague Dawley rats	**Parental:** NOAEL: ♂ =109, ♀ = 416 mg/kg bw/day LOAEL: ♂ = 363, ♀ = 1454 mg/kg bw/day **≥ 363 mg/kg bw/day (♂):** ↓ bw and bwg **Reproductive:** NOAEL: ♂ = 1285 ♀ = 1454 mg/kg bw/day LOAEL: not determined No treatment-related effects at any dose **Offspring:** NOAEL: ♂ =109, ♀ = 125 mg/kg bw/day LOAEL: ♂ = 363, ♀ = 416 mg/kg bw/day **≥ 363/416 mg/kg bw/day:** ↓ bw and bwg **No evidence of offspring sensitivity.**
Prenatal Developmental, oral (gavage) PMRA 1998671 Sprague Dawley rats	**Maternal Toxicity** NOAEL: 1000 mg/kg bw/day LOAEL: not determined No treatment-related effects at any dose. **Developmental Toxicity** NOAEL: 1000 mg/kg bw/day LOAEL: not determined **No evidence of developmental toxicity or sensitivity of the young.**

Study Type/Animal/PMRA #	Study Results
Prenatal Developmental, oral (gavage) PMRA 1998660 NZW rabbits	**Maternal Toxicity** NOAEL: 300 mg/kg bw/day LOAEL: 500 mg/kg bw/day **≥500 mg/kg bw/day:** ↓ bwg and fc **1000 mg/kg bw/day:** abortion (2) **Developmental Toxicity** NOAEL: 500 mg/kg bw/day LOAEL: 1000 mg/kg bw/day **1000 mg/kg bw/day:** abortion (2) **No evidence of sensitivity of the young.**
Bacterial Reverse Mutation Assay (Ames test) PMRA# 1998675	No cytotoxicity **Negative**
In vitro Cell Gene Mutation PMRA# 1998676	No cytotoxicity **Negative**
In vitro Cytogenetics (chromosome aberration) PMRA# 1998677	No cytotoxicity **Negative**
In vivo Cytogenetics (gavage, micronucleus assay) PMRA# 1998678 CD1 mice 5/sex/dose/sampling time	No cytotoxicity **Negative**
Acute Neurotoxicity, oral (gavage) PMRA 1998669 Sprague Dawley rats	NOAEL ♂ = 1000, ♀ = 2000 mg/kg bw/day LOAEL ♂ = 2000 mg/kg bw/day, ♀ = not determined **2000 mg/kg bw:** ↓ bw, bwg and fc (♂) **No evidence of neurotoxicity.**
28-day Immunotoxicity TDAR TDAR, oral (diet) PMRA 1998631 Crlj: CD1 (ICRJ) mice	NOAEL: ♂ = 1056 mg/kg bw/day LOAEL: not determined No treatment-related effects at any dose. **No evidence of immunotoxicity.**
28-day Immunotoxicity TDAR, oral (diet) PMRA 1998633 Sprague Dawley rats	NOAEL: ♂ = 1277 mg/kg bw/day LOAEL: not determined No treatment-related effects at any dose. **No evidence of immunotoxicity.**

Table 4 Toxicology Endpoints for Use in Health Risk Assessment for Aminocyclopyrachlor

Exposure Scenario	Study	Point of Departure and Endpoint	CAF[1] or Target MOE
Acute dietary	Not required		
Repeated dietary	Rat reproductive toxicity study	NOAEL = 109 mg/kg bw/day based on decreased body weight gain	100
	ADI = 1.1 mg/kg bw/day		
Short- and intermediate-term dermal	Rat 28-day dermal toxicity study	NOAEL = 1000 mg/kg bw/day (limit dose)	100
Short- and intermediate-term inhalation[2]	Rat reproductive toxicity study	NOAEL = 109 mg/kg bw/day based on decreased body weight gain	100
Cancer	24 month rat study	Equivocal evidence of brain tumours in males. Endpoints selected for non-cancer risk assessment are protective of this finding.	

[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 and residential assessments

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

Table 5 Integrated Food Residue Chemistry Summary

NATURE OF THE RESIDUE IN GRASS		**PMRA # 1998682**
Radiolabel Position	**[^{14}C]DPX-KJM44 (aminocyclopyrachlor methyl ester)**	
Test Site	Established grass grown outdoors	
Treatment	Single foliar spray application (postemergence)	
Rate	373 g DPX-KJM44/ha/season (equivalent to ~350 g aminocyclopyrachlor/ha)	
End-use product	[^{14}C]DPX-KJM44 (DPX-MAT28 methyl ester)	
Preharvest interval	0 day (after the spray had dried) and 3, 7, 14, 30 and 60 days.	
Matrix	**PHI (days)**	**Radiolabel : [^{14}C]DPX-KJM44 TRR (ppm)**
Grass	0	15.624
	3	15.438
	7	11.998
	14	5.943
	30	4.076
	60	2.447
Metabolites Identified	**Major Metabolites (> 10% TRR)**	**Minor Metabolites (< 10% TRR)**
Radiolabel Position	**[^{14}C]DPX-KJM44**	
Grass (0 and 3 days)	DPX-MAT28, DPX-KJM44	IN-LXT69, IN-QGC48, IN-QFH57, IN-Q3007
Grass (7 days)	DPX-MAT28	DPX-KJM44, IN-LXT69, IN-QGC48, IN-QFH57, IN-Q3007
Grass (14 days)	DPX-MAT28	IN-LXT69, IN-QFH57, IN-Q3007
Grass (30 days)	DPX-MAT28	IN-LXT69, IN-QGC48, IN-QFH57, IN-Q3007
Grass (60 days)	DPX-MAT28	IN-LXT69, IN-QGC48, IN-QFH57, IN-Q3007, IN-V0977

Proposed metabolic scheme in grass:
The metabolism of aminocyclopyrachlor methyl ester in grass is characterised by the following metabolic processes:

- DPX-KJM44 (aminocyclopyrachlor methyl ester) was rapidly metabolized (demethylated) to aminocyclopyrachlor (DPX-MAT28).
- DPX-MAT28 was decarboxylated to form IN-LXT69.
- Pyrimidine ring opening (presumably through the postulated intermediate IN-YY905 – plausible intermediate compound proposed by the study author but not detected in the study) with subsequent oxidations to the amine and carboxylic acid compounds, IN-Q3007 and IN-V0977.
- DPX-KJM44 and DPX-MAT28 also underwent (a proposed) photo-induced elimination of hydrogen chloride with concomitant pyrimidine ring contraction (as a minor pathway) yielding the imidazole-nitriles, IN-QFH57 and IN-QGC48, respectively.

NATURE OF THE RESIDUE IN LACTATING GOAT | **PMRA # 1998681**

[^{14}C]DPX-KJM44 (methyl ester of aminocyclopyrachlor; specific activity: 1.64 Bq/mg) was administrated to one lactating goat at an average dose of 97 mg/kg feed (corresponding to 2.94 mg/kg bw/day). The radiolabelled compound was administrated orally by gelatin capsule twice daily for five consecutive days. Milk was collected twice a day and the excreta was collected once a day throughout the study period. The animal was sacrificed approximately 6 hours following the last administration and the following tissues were collected for analysis: liver, kidney, fat, muscle, GIT and its contents, and bile.

Matrices	**% of Administered Dose**
	Radiolabel: [^{14}C]DPX-KJM44
Urine and feces	74.1
Muscle	0.0 (0.042 ppm)
Fat	0.0 (0.010, 0.016, 0.026 ppm)
Kidney	0.03 (1.673 ppm)
Liver	0.04 (0.299 ppm)
Milk	0.032 [cumulative] (avg.: 0.025 ppm)

Metabolites identified	**Major Metabolites (> 10% TRR)**	**Minor Metabolites (< 10% TRR)**
Radiolabel Position	**[^{14}C]DPX-KJM44**	**[^{14}C]DPX-KJM44**
Muscle	Aminocyclopyrachlor	–
Fat	Aminocyclopyrachlor	–
Kidney	Aminocyclopyrachlor	–
Liver	Aminocyclopyrachlor	–
Milk	Aminocyclopyrachlor	–

Proposed Metabolic Scheme in Livestock
Aminocyclopyrachlor methyl ester (DPX-KJM44) was metabolized in the goat and eliminated as aminocyclopyrachlor (DPX-MAT28), primarily in the excreta (74.1% of the administrated dose).

STORAGE STABILITY | **PMRA # 1998292**

Samples of grass forage and hay were spiked with aminocyclopyrachlor (DPX-MAT 28), aminocyclopyrachlor methyl ester (DPX-KJM44) and IN-LXT69 at 0.50 ppm each for forage and 1.0 ppm each for hay. The samples were stored frozen (–20 °C) and analyzed at the target intervals of 0, 7, 14, 30, 60, 90, 150, 210, 300, 360 and 500 days. The results showed that aminocyclopyrachlor (acid), aminocyclopyrachlor methyl ester and the metabolite IN-LXT69 were stable in/on grass forage and hay for up to 499–502 days.

CROP FIELD TRIALS - grass | **PMRA # 1998293**

Twenty two field trials were conducted in Zone 1 (3 trials), Zone 2 (1 trial), Zone 5 (6 trials), Zone 6 (3 trials), Zone 7 (2 trials), Zone 8 (1 trial) and Zone 14 (6 trials).

Treated plots received a single foliar broadcast application of an 80% water dispersible granule (WG) formulation of DPX-KJM44 (aminocyclopyrachlor methyl ester) at a rate of 328–357 g a.i./ha, equivalent to 308–335 g a.e./ha DPX-MAT28 (aminocyclopyrachlor – acid) with spray volumes of 94–281 L/ha.

Part 1. Residues from Field Trials with Aminocyclopyrachlor Methyl Ester (DPX-KJM44) (80% WG Formulation).									
Commodity	Total Applic. Rate [1] (g a.i./ha)	PHI (days)	Residue Levels (ppm)						
			n	Min. [#]	Max. [#]	HAFT*	Median* (STMdR)	Mean* (STMR)	SD*
Aminocyclopyrachlor methyl ester (DPX-KJM44)									
Grass forage	328–357	0	22	7.70	47.0	46.5	22.0	22.9	10
Grass hay			22	13.0	108	103	30.0	38.4	20
Aminocyclopyrachlor (DPX-MAT 28)									
Grass forage	328–357	0	22	0.76	14.0	13.0	2.28	3.17	3
Grass hay			22	2.40	80.0	78.5	15.8	18.2	16
Combined residues of aminocyclopyrachlor and aminocyclopyrachlor methyl ester (in aminocyclopyrachlor equivalents) [2]									
Grass forage	328–357	0	22	8.21	50.6	50.2	23.5	24.6	11
Grass hay			22	26.4	126	122	47.7	54.2	26
IN-LXT69 (metabolite)									
Grass forage	328–357	0	22	<0.01	0.03	0.03	0.01	0.01	0.01
Grass hay			22	0.01	0.08	0.08	0.02	0.03	0.01
Part 2. Residues from Field Trials with Aminocyclopyrachlor (DPX-MAT 28) (50% SL Formulation).									
Commodity	Total Applic. Rate [3] (g a.e./ha)	PHI (days)	Residue Levels (ppm)						
			n	Min. [#]	Max. [#]	HAFT*	Median* (STMdR)	Mean* (STMR)	SD*
Aminocyclopyrachlor methyl ester (DPX-KJM44)									
Grass forage	308–317	0	6	0.01	0.15	0.15	0.03	0.05	0.0
Grass hay			6	0.06	0.89	0.73	0.15	0.24	0.2
Aminocyclopyrachlor (DPX-MAT 28)									
Grass forage	308–317	0	6	12.0	41.0	39.0	20.5	22.6	9.2
Grass hay			6	29.0	58.0	48.5	42.5	40.8	7.4
Combined residues of aminocyclopyrachlor and aminocyclopyrachlor (in aminocyclopyrachlor equivalents) [2]									
Grass forage	308–317	0	6	12.0	41.1	39.1	20.5	22.6	9.2
Grass hay			6	29.2	58.8	49.2	42.6	40.9	7.5
IN-LXT69 (metabolite)									
Grass forage	308–317	0	6	<0.01	0.04	0.03	0.01	0.02	0.01
Grass hay			6	0.01	0.11	0.11	0.04	0.05	0.04
Part 3. Residues from Side-by-Side Trials with Aminocyclopyrachlor Methyl Ester (DPX-KJM44) (80% WG Formulation) Using High and Low Volume.									
Commodity	Total Applic. Rate [1] (g a.i./ha)	PHI (days)	Residue Levels (ppm)						
			n	Min. [#]	Max. [#]	HAFT*	Median* (STMdR)	Mean* (STMR)	SD*
High Volume Application									
Aminocyclopyrachlor methyl ester (DPX-KJM44)									
Grass forage	337–338	0	3	13.0	35.0	34.0	25.5	24.5	10
Grass hay			3	13.0	47.0	46.0	34.0	31.8	15
Aminocyclopyrachlor (DPX-MAT 28)									
Grass forage	337–338	0	3	0.99	2.00	1.95	1.55	1.53	0.4
Grass hay			3	4.00	29.0	27.0	4.50	11.9	13
Combined residues of aminocyclopyrachlor and aminocyclopyrachlor (in aminocyclopyrachlor equivalents) [2]									
Grass forage	337–338	0	3	13.4	34.4	33.5	25.9	24.5	10
Grass hay			3	31.4	48.4	47.3	41.5	41.8	5

IN-LXT69 (metabolite)									
Grass forage	337–338	0	3	<0.01	0.03	0.02	0.02	0.02	0.01
Grass hay			3	0.01	0.03	0.03	0.02	0.02	0.01
Low Volume Application									
Aminocyclopyrachlor methyl ester (DPX-KJM44)									
Grass forage	323–335	0	3	9.50	14.0	13.5	10.8	11.4	2
Grass hay			3	19.0	31.0	27.0	22.5	23.0	4
Aminocyclopyrachlor (DPX-MAT 28)									
Grass forage	323–335	0	3	0.43	0.84	0.75	0.71	0.66	0.1
Grass hay			3	1.10	14.00	12.00	2.40	5.18	5.9
Combined residues of aminocyclopyrachlor and aminocyclopyrachlor (in aminocyclopyrachlor equivalents) [2]									
Grass forage	323–335	0	3	9.34	13.9	13.4	10.6	11.3	2
Grass hay			3	18.9	43.14	37.4	23.5	26.8	9
IN-LXT69 (metabolite)									
Grass forage	323–335	0	3	<0.01	<0.01	<0.01	<0.01	0.01	0.0
Grass hay			3	0.01	0.02	0.02	0.01	0.01	0.0

[1] The application rate is for aminocyclopyrachlor methyl ester (DPX-KJM44).
[2] The combined residues were calculated in terms of aminocyclopyrachlor equivalents using the following conversion: (ppm DPX-MAT 28) + (ppm DPX-KJM44 × [213.62 mw DPX-MAT 28 / 227.65 mw DPX-KJM44]).
[3] The application rate is for aminocyclopyrachlor (DPX-MAT 28).
n = number of trials
[#] Values based on total number of samples.
[*] Values based on per-trial averages. HAFT = Highest Average Field Trial, SD = Standard Deviation. For computation of the HAFT, median, mean and standard deviation, values <LOQ are assumed to be at the LOQ.

LIVESTOCK FEEDING – Dairy cattle	**PMRA # 1998296, 1998297, 1998298**

Four groups of dairy cows (3 cows/group; Groups 1–4) were dosed orally once a day with gelatin capsules containing aminocyclopyrachlor methyl ester (DPX-KJM44) at target doses of 1.8, 3.6, 10.8, and 36 mg/kg bw/day for 28 consecutive days (equivalent to 73, 160, 455, and 1595 ppm in the diet (dry-weight basis).
For the calculations, 0.01 ppm (LOQ) was used for values <LOQ. Residues are reported for aminocyclopyrachlor only.

Matrix	**Feeding Level (ppm/d)**	**n**	**LOD**	**Min**	**Max**	**Median**	**Mean**	**Standard Deviation**
Whole milk	73	21	0.0029	<0.01	<0.01	0.01	0.01	NA
Muscle		3	0.0052	<0.01	<0.01	0.01	0.01	NA
Liver		3	0.0032	<0.01	0.082	0.028	0.040	0.037
Kidney		3	0.001	0.092	0.17	0.11	0.124	0.041
Fat		3	0.0008	<0.01	0.015	0.010	0.012	0.003
Whole milk	160	21	0.0029	<0.01	0.012	0.010	0.010	0.001
Muscle		3	0.0052	<0.01	0.012	0.010	0.011	0.001
Liver		3	0.0032	0.020	0.064	0.042	0.042	0.022
Kidney		3	0.001	0.23	0.40	0.29	0.307	0.086
Fat		3	0.0008	<0.01	0.040	0.010	0.020	0.017
Whole milk	455	21	0.0029	0.016	0.026	0.021	0.021	0.003
Muscle		3	0.0052	<0.01	<0.01	0.01	0.01	NA
Liver		3	0.0032	0.025	0.075	0.046	0.049	0.025
Kidney		3	0.001	0.20	0.54	0.28	0.34	0.178
Fat		3	0.0008	0.029	0.120	0.040	0.063	0.050
Whole milk	1595	25	0.0029	0.040	0100	0.060	0.063	0.019
Muscle		3	0.0052	0.021	0.10	0.030	0.050	0.043
Liver		3	0.0032	0.088	0.110	0.091	0.096	0.012
Kidney		3	0.001	0.680	1.4	0.850	0.977	0.376

Fat		3	0.0008	0.025	0.740	0.610	0.458	0.381

Commodity	Feeding level (ppm)	Maximum Residues (ppm)	MBD (ppm)		Anticipated Residue (ppm)	
			Beef/Dairy	Hog	Beef/Dairy	Hog
Milk	160	0.012	91.08	NA	0.007	NA
Fat	160	0.040	91.08	NA	0.023	NA
Kidney	160	0.40	91.08	NA	0.228	NA
Liver	73/160	0.082	91.08	NA	0.102	NA
Muscle	160	0.012	91.08	NA	0.007	NA

Table 6 Food Residue Chemistry Overview of Metabolism Studies and Risk Assessment

PLANT STUDIES			
RESIDUE DEFINITION FOR ENFORCEMENT Primary crops (Grass)	Not established		
RESIDUE DEFINITION FOR RISK ASSESSMENT Primary crops	Not established		
METABOLIC PROFILE IN DIVERSE CROPS	The profile in diverse crops cannot be determined, because only grass was investigated.		
ANIMAL STUDIES			
ANIMALS	**Ruminant**		
RESIDUE DEFINITION FOR ENFORCEMENT	Aminocyclopyrachlor (acid)		
RESIDUE DEFINITION FOR RISK ASSESSMENT	Aminocyclopyrachlor (acid)		
METABOLIC PROFILE IN ANIMALS (goat, hen, rat)	The profile is similar in goat and rat.		
FAT SOLUBLE RESIDUE	Yes		
DIETARY RISK FROM FOOD AND WATER			
	POPULATION	**ESTIMATED RISK % of ACCEPTABLE DAILY INTAKE (ADI)**	
		Food Only	**Food and Water**
Basic chronic dietary risk **ADI = 1.09 mg/kg bw/day** **Estimated chronic drinking water concentration = 55 μg/L**	**All infants < 1 year**	<1	0.4
	Children 1–2 years	<1	0.2
	Children 3 to 5 years	<1	0.2
	Children 6–12 years	<1	0.1
	Youth 13–19 years	<1	0.1
	Adults 20–49 years	<1	0.1
	Adults 50+ years	<1	0.1
	Total population	<1	0.1

Table 7 Fate and Behaviour of Aminocyclopyrachlor in the Environment

Transformation process		Half-life (d)	Model	Transformation products		Environmental importance	PMRA #
				major	minor		
Abiotic transformation							
hydrolysis		Stable in an environmentally relevant pH range				Not an important transformation process	1998693
photo-transformation	soil	111	SFO	none	IN-LXT69 Up to 14 unknowns	Not an important transformation process	1998694
	pH 4 buffer	14.6	SFO	IN-LXT69 IN-QFH57 IN-V0977	IN -Q3007 IN-YY905 4 unknowns	Can be an important transformation process	1998695
	Natural water	2.6	SFO	IN-QFH57 IN-V0977 IN-Q3007 IN-YY905 2 unknowns	3 unknowns		
	air	Insignificant volatilization				Not an important transformation process	N/A
Biotransformation							
Aerobic soil	sandy loam	435	SFO	None	IN-LXT69 CO_2	Persistent	1998696
	silty clay	118	SFO	none	IN-LXT69 CO_2	Moderately persistent	
	clay loam	126	SFO	none	IN-LXT69 CO_2	Moderately persistent	
	sandy loam	276	SFO	CO_2	IN-LXT69	Persistent	2121783
Anaerobic soil (flooded)	silty loam	1733	SFO	none	IN-LXT69 CO_2	Persistent	1998551
Aerobic water-sand sediment		water: 445	SFO	none	None	Persistent 60 – 80% AR remained in water	1998698
		total system: 2316	SFO				
Aerobic water-silty loam sediment		Water: 385	DFOP	none	None	Persistent > 60% AR remained in water	
		Total system: 1207	SFO				
Anaerobic water-silty loam sediment		Water: 595	SFO	none	None	Persistent > 60% AR remained in water	1998697
		Total system: 5140	SFO				
Mobility							
Adsorption/desorption in soil		K_d: 0.01 to 0.86 mL/g K_{oc}: 1.55 to 22.65 mL/g K_{desorb}: 0.002–0.47 mL/g				Very high mobility	1998699
Terrestrial field dissipation study							
Ontario bare soil		176	DFOP	Detected throughout the		Leaching as a	1998301

Transformation process	Half-life (d)	Model	Transformation products		Environmental importance	PMRA #
			major	minor		
(applied as 25 WP ester formulation)			profile (90 cm). No major transformation product.		major dissipation route	
Manitoba bare soil (applied as 80 WG ester formulation)	462	DFOP	Detected throughout the profile (90 cm). No major transformation product.		Leaching as a major dissipation route	1998302

Table 8 Effects of Aminocyclopyrachlor on Terrestrial and Aquatic Organisms

Organism	Exposure	Endpoint value		Degree of toxicity[a]	PMRA#
Terrestrial invertebrates					
Earthworm	14 d Acute	LC_{50}: > 1000 mg a.i./kg dw soil NOEC: 1000 mg a.i./kg dw soil			1998701
Bee	48 h Oral	LC_{50}: > 100 µg a.i./bee NOEC: 100 µg a.i./bee		Relatively non-toxic	1998702
	48 h Contact	LC_{50}: > 112.03 µg a.i./bee NOEC: 112.03 µg a.i./bee			
Birds					
Northern Bobwhite	Acute oral	LD_{50}: > 2075 mg a.i./kg bw NOEL: 2075 mg a.i./kg bw		Practically non-toxic	1998711
	8 d Dietary	LD_{50}: >5660 mg a.i./kg diet NOEL: 1194 mg a.i./kg bw/day		Practically non-toxic	1998713
	22 wk Reproduction	NOEC: 994 mg a.i./kg dw diet NOEL: 102 mg a.i/kg bw/day			1998715/ 1998716
Mallard	8 d Dietary	LD_{50}: >5340 mg a.i./kg diet NOEL: 2440 mg a.i./kg bw/day		Practically non-toxic	1998714
	22 wk Reproduction	NOEC: 994mg a.i./kg dw diet NOEL: 126 mg a.i/kg bw/day			1998717/ 1998718
Mammals					
Rat	Acute oral	LD_{50}: > 5340 mg a.i./kg bw ♀		Practically non-toxic	1998609
	Reproduction	NOAEL: 109 mg a.i./kg bw/day			1998662
Terrestrial vascular plants					
Vascular plant	21 d Seedling emergence	Monocot	ER_{25}: 13.8 g a.e./ha		1998723
		dicot	ER_{25}: 0.5 g a.e./ha		
		HC_5: 2.37 g a.e./ha			
	21 d Vegetative vigour	Monocot	EC_{25}: 58.4 g a.e./ha $NOEC/EC_{05}$: 25 g a.e./ha		1998724
		dicot	EC_{25}: 0.025 g a.e./ha $NOEC/EC_{05}$: 0.049 g a.e./ha		
		HC_5: 0.215 g a.e./ha			
Freshwater invertebrates					
Daphnia magna	48 h Acute	LC_{50}: > 39.7 mg a.i./L NOEC: 3.7 mg a.i./L		Slightly toxic	1998703
	21 d Chronic	LC_{50}: > 9.9 mg a.i./L NOEC: 4.9 mg a.i./L		Slightly toxic	2103309
Fresh water fish					
Rainbow trout	96 h Acute	LC_{50}/EC_{50}: > 122 mg a.i./L NOEC: 122 mg a.i./L		Practically non-toxic	1998707

Organism	Exposure	Endpoint value	Degree of toxicity[a]	PMRA#
	90 d Chronic	LC_{50}: > 11 mg a.i./L NOEC: 11 mg a.i./L		1998710
Bluegill sunfish	96 h Acute	LC_{50}: >120 mg a.i./L NOEC: 120 mg a.i./L	Practically non-toxic	1998708
Freshwater algae				
Green alga (*pseudokirchneriella subcapitata*)	72 h Acute	EC_{50}: > 120 mg a.i./L NOEC: 59.1 mg a.i./L		1998720
Green-blue alga (*aneabena flos-aqua*)	96 h Acute	EC_{50}: > 6.52 mg a.i./L NOEC: 0.36 mg a.i./L		1998721
		EC_{50}: > 119 mg a.i./L NOEC: 11.3 mg a.i./L		
Freshwater Diatom (*Navicula pelliculosa*)	96 h Acute	EC_{50}: 27.3 mg a.i./L NOEC/EC_{05}: 14 mg a.i./L		1998719
		EC_{50}: 35.7 mg a.i./L NOEC: 14 mg a.i./L		
Aquatic vascular plant				
Duckweed (*Lemna gibba G3*)	7 d Dissolved	EC_{50}: 84.7 mg a.i./L NOEC: 3.7 mg a.i./L		1998725
Marine species				
Mysid shrimp (*Americamysis bahia*)	96 h Acute	LC_{50}: > 122 mg a.i./L NOEC: 122 mg a.i./L	Practically non-toxic	1998705
Eastern oyster (*Crassostrea virginica*)	96 h Acute	EC_{50}: > 118 mg a.i./L NOEC: 67 mg a.i./L	Practically non-toxic	1998706
Sheephead minnow (*Cyprinodon variegatus*)	96 h Acute	LC_{50}: > 129 mg a.i./L NOEC: 129 mg a.i./L	Practically non-toxic	1998709
Saltwater diatom (*Skeletonema costatum*)	96 h Acute	EC_{50}: > 120 mg a.i./L NOEC: 120 mg a.i./L		1998722

Table 9 Screening Level Risk Assessment to Terrestrial Non-Target Invertebrates and Vascular Plants

Organism	Exposure	Endpoint value	EEC	RQ	LOC exceeded?
Earthworm	Acute	> 1000 mg a.i./kg dw soil	0.12 mg a.i./kg soil	< 0.01	No
Bee	Acute oral	> 100 µg a.i./bee	264 g a.i./ha	< 0.01	No
	Acute contact	> 112.03 µg a.i./bee		< 0.01	No
Vascular plants	Seedling emergence	2.37 g a.i./ha	70 g a.i./ha (DPX-MAT 28 Herbicide)	29.5	Yes
			264 g a.i./ha (Navius Herbicide)	111	Yes
	Vegetative vigour	0.215 g a.i./ha	70 g a.i./ha (DPX-MAT 28 Herbicide)	326	Yes
			264 g a.i./ha (Navius Herbicide)	1228	Yes

Table 10 Risk to Birds and Mammals as a Result of Direct On-Field Exposure

Organism weight (g)	FIR[a] (g dw diet/day)	Endpoint	Endpoint value (mg a.i./kg bw/day)	Feeding Guild (food item)	EDE[b] (mg a.i./kg bw/day)	RQ	LOC exceeded?
Birds							
20 g	5.1	Acute	207.5	Insectivore (small insects)	13.30	0.06	No
		Reproduction	102.0	Insectivore (small insects)	13.30	0.13	No
100 g	19.9	Acute	207.5	Insectivore (small insects)	10.38	0.05	No
		Reproduction	102.0	Insectivore (small insects)	10.38	0.10	No
1000 g	58.1	Acute	207.5	Herbivore (Short grass)	10.83	0.05	No
		Reproduction	102.0	Herbivore (Short grass)	10.83	0.11	No
Mammals							
15 g	2.2	Acute	500.0	Insectivore (small insects)	7.65	0.02	No
		Reproduction	109	Insectivore (small insects)	7.65	0.07	No
35 g	4.5	Acute	500.0	Herbivore (Short grass)	23.97	0.05	No
		Reproduction	109	Herbivore (Short grass)	23.97	0.22	No
1000 g	68.7	Acute	500.0	Herbivore (Short grass)	12.81	0.03	No
		Reproduction	109	Herbivore (Short grass)	12.81	0.12	No

[a] Food Ingestion Rates (Nagy, 1987). For generic birds with body weight less than or equal to 200 g, the "passerine" equation was used; for generic birds with body weight greater than 200 g, the "all birds" equation was used:
Passerine Equation (body weight < or =200 g): FIR (g dry weight/day) = $0.398(\text{BW in g})^{0.850}$
All birds Equation (body weight > 200 g): FIR (g dry weight/day) = $0.648(\text{BW in g})^{0.651}$.
For mammals, the "all mammals" equation was used: FIR (g dry weight/day) = $0.235(\text{BW in g})^{0.822}$
[b] EDE = Estimated daily exposure; is calculated using the following formula: (FIR/BW) × EEC.
At the screening level, food items representing the most conservative EEC for each size guild are used.

Table 11 Refined Risk Assessment for Off-Field Exposure to End-use Products

Product	Active ingredient	Application rate g a.i./ha	Endpoint g a.i./ha	Off-field[1]				LOC exceeded ?
				60% drift (aerial, coarse droplets)		3% drift (ground, coarse droplets)		
				EEC g a.i./ha	RQ	EEC g a.i./ha	RQ	
DPX-MAT 28 Herbicide	Vegetative vigour	70	HC_5 0.215	42	195	2.1	9.8	Yes
Truvist Herbicide	DPX-MAT28	66.4	HC_5 0.215	42	195	2.1	9.8	Yes
	Chlorsulfuron[1]	26.5	EC_{25} 0.011	N/A	N/A	0.80	72.3	Yes
Navius Herbicide	DPX-MAT28	264	HC_5 0.215	158.4	737	7.92	36.8	Yes
	Metsulfuron-methyl	84.2	EC_{25} 0.02	50.5	2526	2.53	126.3	Yes
Rejuvra XL Herbicide	DPX-MAT28	60	HC_5 0.215	36	167	1.8	8.4	Yes
	Metsulfuron-methyl	30	EC_{25} 0.02	18	900	0.9	45	Yes

[1]aerial application of chlorsulfuron is not registered.

Table 12 Screening Level Risk to Aquatic Organisms

Organism	Exposure	Endpoint value (mg a.i./L)	EEC (mg a.i./L)	RQ	LOC exceeded?
Freshwater species					
Daphnia magna	Acute	> 39.7	0.033	< 0.01	No
	Chronic	4.9	0.033	< 0.01	
Amphibian	Acute	> 120	0.18	< 0.02	No
	Chronic	11	0.18	0.02	
Fresh water fish	Acute	> 120	0.033	< 0.01	No
	Chronic	11	0.033	< 0.01	
Freshwater alga	Acute	6.5	0.033	0.01	No
Vascular plant	Dissolved	84.7	0.033	< 0.01	No
Marine species					
Crustacean	Acute	> 122	0.033	< 0.01	No
Mollusk	Acute	> 118	0.033	< 0.01	No
Salt water fish	Acute	> 129	0.033	< 0.01	No
Marine alga	Acute	> 120	0.033	< 0.01	No

Table 13a Use Claims Accepted for DPX-MAT 28 Herbicide

Accepted label claim/use direction
Use sites: DPX-MAT 28 Herbicide may be applied to pasture, rangeland, and non-crop areas, such as utility rights of way, roadsides, industrial sites and fencelines.
Pest (efficacy) claims: Refer to Table 13b below.
Application rates: 30, 35 or 70 g a.i./ha (60, 70 or 140 g product/ha)
Adjuvants: Application is to be made with one of the following surfactant options: a non-ionic surfactant at 0.25% v/v, a crop oil concentrate at 1% v/v or Merge Adjuvant at 1% v/v.
Application timing: when weeds are young and actively growing or between mid-June and mid-August.
Application method: Application by ground equipment in 200 L/ha spray volume or by aerial equipment in 30–50 L/ha spray volume.
Maximum number of applications per year: one at the highest rate and two at either of the lower rates (maximum annual application rate of 70 g a.i./ha)
Rainfast interval (minimum interval between time of application and a rain event): one hour
Tank mixes: DPX-MAT 28 Herbicide may be tank mixed with other herbicides that are registered for the same use sites.
Invasive plant species: DPX-MAT 28 Herbicide may be used as a component of integrated vegetation management programs aimed at controlling common crupina, Iberian starthistle, South African ragwort and yellow starthistle.
Regional restrictions for use: There are no regional restrictions for DPX-MAT 28 Herbicide.

Table 13b Acceptable Pest Claims for DPX-MAT 28 Herbicide

Weed species	30 g a.i./ha or 60 g product/ha	35 g a.i./ha or 70 g product/ha	70 g a.i./ha or 140 g product/ha
Balsam poplar	–	–	12 month control
Canada thistle	Season-long suppression		12 month control
Dandelion	Season-long suppression	12 month suppression	12 month control
Fleabane, Canada	–	–	Suppression
Fleabane, annual	–	–	Suppression
Giant hogweed	Season-long control (up to 4-leaf stage)		
Hawkweed (orange and yellow)	–	–	12 month control
Knapweed, spotted	–	12 month suppression	12 month control
Knapweed, diffuse	–	12 month suppression	12 month control
Knapweed, Russian	–	12 month suppression	12 month control
Kochia (including Group 2 resistant)	–	Suppression (< 15 cm)	Control
Leafy spurge	12 month suppression		
Nodding thistle (musk, plumeless, spiny plumeless)	12 month suppression	Season-long control	12 month control
Plantain species	Season-long suppression		Season-long control
Smooth bedstraw	12 month control		
Annual sow thistle	–	Suppression	Control
Perennial sow thistle	–	12 month suppression	12 month control
Sumac (staghorn and smooth)	–	–	12 month control
Trembling aspen	–	–	12 month suppression
Wild carrot	–	–	12 month control

Where there is no claim indicated for a higher rate, the claim is the same as for the lower rate(s).

Table 14a Use Claims Accepted for Truvist Herbicide

Accepted label claim/use direction
Use sites: Truvist Herbicide may only be applied to non-crop areas, including industrial grassed sites, as indicated below: - uncultivated non-agricultural areas (such as airports, highway, railroad and utility rights-of-way, sewage disposal areas, etc.) - uncultivated agricultural areas - non-crop producing (such as farmyards, fuel storage areas, fence rows, non-irrigation ditchbanks, barrier strips, etc.) - industrial sites - outdoor (such as lumberyards, pipeline and tank farms, etc.).
Pest (efficacy) claims: Refer to Table 14b below.
Application rate: 92.9 g a.i./ha (168 g product/ha)
Adjuvants: Application is to be made with one of the following surfactant options: a non-ionic surfactant at 0.25% v/v, a crop oil concentrate at 1% v/v or Merge Adjuvant at 1% v/v.
Application timing: when weeds are young and actively growing, or typically June-July for annual weeds.
Application method: ground application equipment in a minimum spray volume of 200 L/ha.
Maximum number of applications per year: one
Rainfast interval (minimum interval between time of application and a rain event): four hours
Tank mixes: Truvist Herbicide may be tank mixed with other herbicides that are registered for the same use sites.
Invasive plant species: Truvist Herbicide may be used as a component of integrated vegetation management programs aimed at controlling common crupina, Iberian starthistle, South African ragwort, yellow starthistle and halogeton (saltlover).
Regional restrictions for use: There are no regional restrictions for DuPont Truvist Herbicide.

Table 14b Acceptable Pest Claims for Truvist Herbicide

Pest	Claim supported
Bladder campion	12 month control
Bluebur	Control
Buttercup, Tall (giant), Bulbous	Season-long control
Buttercup, Hairy, Small-flowered	Control
Canada thistle	Control
Common chickweed	Control
Common groundsel	Control
Common tansy	12 month control
Common yarrow	Control
Corn spurry	Control
Cow cockle	Control
Dandelion	Control
Field bindweed	Season-long control

Pest	Claim supported
Field horsetail	12 month control
Fleabane, Canada	Control
Fleabane, Annual	Suppression
Flixweed	Control
Giant hogweed	Season-long control (up to 4-leaf)
Goldenrod (Canada, common)	Season-long control
Green smartweed	Control
Halogeton	Control
Hawkweed (Orange, Yellow)	Control
Hemp nettle	Control
Knapweed (diffuse, spotted)	Control
Knotweed (Silversheath, Prostrate, Common, Erect)	Control
Kochia (including Group 2 resistant)	Control
Kudzu	Suppression
Lady's thumb	Control
Lamb's quarters	Control
Leafy spurge	Control
Nodding (Musk, Plumeless, Spiny Plumeless) thistle	Control
Ox-eye daisy	Control
Pasture sage	Control
Perennial pepperweed	12 month control
Plantain species	Season-long control
Poison ivy	12 month control
Prickly lettuce	Control
Ragweed, Common	Control
Ragweed, Giant	Control
Ragweed, Western	Season-long control
Redroot pigweed	Control
Russian thistle	Control (up to 8 cm)
Scentless chamomile	Control
Shepherd's purse	Control
Skeletonweed	12 month control
Smooth bedstraw	Control
Sow thistle (annual and perennial)	Control
Stinkweed	Control
Stork's bill	Control
Sumac (staghorn, smooth)	12 month control
Sweet clover (white, yellow)	Season-long control
Volunteer canola	Control
White cockle	Control
Wild buckwheat	Control
Wild carrot	Control
Wild chervil	Season-long control

Pest	Claim supported
Wild mustard	Control
Wild parsnip	Control
Wild rose	Season-long control
Yellow starthistle	Control
Willow species (pussy, sandbar, ditchbank)	12 month suppression
Snowberry (Western)	Suppression

Table 15a Use Claims Accepted for Navius Herbicide

Accepted label claim/use direction
Use sites: Navius Herbicide may be applied to rangeland and non-crop areas, such as utility rights of way, roadsides, industrial sites and fencelines.
Pest (efficacy) claims: Refer to Table 15b below.
Application rates: 87, 174, 260 or 348 g a.i./ha (167, 334, 499 or 668 g product/ha)
Adjuvants: Application is to be made with one of the following surfactant options: a non-ionic surfactant at 0.25% v/v, a crop oil concentrate at 1% v/v or Merge Adjuvant at 1% v/v.
Application timing: when brush species and weeds are actively growing. Application to brush should be made after the target species have leafed out.
Application method: Application by ground equipment, as either a low volume foliar broadcast (500 L/ha) or high volume foliar broadcast (1000–2000 L/ha) or by aerial equipment in 30–50 L/ha spray volume.
Maximum number of applications per year: based on maximum annual application rate of 348 g a.i./ha/year (for example, one at the highest rate)
Rainfast interval (minimum interval between time of application and a rain event): four hours
Tank mixes: Navius Herbicide may be tank mixed with other herbicides that are registered for the same use sites.
Invasive plant species: Navius Herbicide may be used as a component of integrated vegetation management programs aimed at controlling common crupina, Iberian starthistle, South African ragwort and yellow starthistle.
Regional restrictions for use: There are no regional restrictions for Navius Herbicide.

Table 15b Acceptable Pest Claims for Navius Herbicide

87 g a.i./ha or 167 g product/ha	
Weeds Controlled	
Annual sowthistle Ball mustard Bluebur Canada goldenrod* Canada thistle Chickweed Common groundsel Common tansy Common yarrow Corn spurry Cow cockle Dandelion Diffuse knapweed Flixweed Giant buttercup* Giant hogweed* (up to 4-leaf) Green smartweed Hemp-nettle Kochia (including ALS-resistant) Lady's-thumb Leafy spurge Norwegian cinquefoil* Orange hawkweed	Ox-eye daisy Perennial sowthistle Prostrate pigweed Redroot pigweed Russian thistle Scentless chamomille Shepherd's-purse Spotted knapweed Stinkweed Stork's-bill Sumac (smooth, staghorn) Sweet clover (white, yellow) Tartary buckwheat Volunteer canola (except Clearfield varieties) Western snowberry White cockle Wild carrot Wild mustard Wild rose Yellow starthistle
*season-long control	
Weeds Suppressed	
Lamb's-quarters Toadflax Wild buckwheat	

174 g a.i./ha or 334 g product/ha		
Brush Species Controlled		**Maximum height**
Manitoba maple (Box Elder)	*Acer negundo*	
Red maple	*Acer rubrum*	
Sugar maple	*Acer saccharum*	
Black tupelo	*Nyssa sylvatica*	(< 1 metre height)
Common sassafras	*Sassafras albidum*	
Green ash	*Fraxinus pennsylvanica*	
White ash	*Fraxinus americana*	
Black cherry	*Prunus serotina*	< 3 metres height
Chokecherry	*Prunus virginica*	< 3 metres height
Pin cherry	*Prunus pensylvanica*	< 3 metres height

Balsam poplar	*Populus balsamifera*	
Trembling aspen	*Populus tremuloides*	< 3 metres height
Plains cottonwood	*Populus sargentii*	
Black poplar	*Populus nigra*	
Sandbar / Ditchbank willow	*Salix exigua or S. interior*	
Large pussy willow	*Salix discolor*	
Yellow poplar (tulip tree)	*Liriodendron tulipifera*	
Tree of heaven	*Alianthus altissima*	
Hackberry	*Celtis occidentalis*	
Balsam fir	*Abies balsamea*	< 2 metre height
Douglas fir	*Pseudotsuga menziesii*,	< 2 metre height
Black spruce	*Picea mariana*	< 2 metres height
Norway spruce	*Picea abies*	< 2 metres height
White spruce	*Picea glauca*	< 2 metres height
260 g a.i./ha or 499 g product/ha		
Brush Species Controlled		**Maximum height**
Black oak	*Quercus velutina*	
Northern red oak	*Quercus rubra*	
Bitternut hickory	*Carya cordiformus*	< 2 metres in height
Pignut hickory	*Carya glabra*	< 2 metres in height
348 g a.i./ha or 668 g product/ha		
Brush Species Controlled		**Maximum height**
Eastern white pine	*Pinus strobus*	< 2 metres in height
Jack pine	*Pinus banksiana*	< 2 metres in height
Red pine	*Pinus resinosa*	< 2 metres in height
Western white pine	*Pinus monticola*	< 2 metres in height
Balsam fir	*Abies balsamea*	2–3 metres in height
Douglas fir	*Pseudotsuga menziesii*,	2–3 metres in height
Black spruce	*Picea mariana*	2–3 metres in height
Norway spruce	*Picea abies*	2–3 metres in height
White spruce	*Picea glauca*	2–3 metres in height

Table 16a Use Claims Accepted for Rejuvra XL Herbicide

Accepted label claim/use direction
Use sites: Rejuvra XL Herbicide may be applied to pasture, rangeland, and non-crop areas, such as utility rights of way, roadsides, industrial sites and fencelines.
Pest (efficacy) claims: Refer to Table 16b below.
Application rates: 45 or 90 g a.i./ha (85 or 170 g product/ha)
Adjuvants: Application is to be made with one of the following surfactant options: a non-ionic surfactant at 0.25% v/v, a crop oil concentrate at 1% v/v or Merge Adjuvant at 1% v/v.

Accepted label claim/use direction
Application timing: when weeds are young and actively growing (< 10 cm tall or across), or between mid-June and mid-August.
Application method: Application by ground equipment in 200 L/ha spray volume or by aerial equipment in 30–50 L/ha spray volume.
Maximum number of applications per year: one at the higher rate and two at the lower rate (maximum annual application rate of 90 g a.i./ha)
Rainfast interval (minimum interval between time of application and a rain event): four hours
Tank mixes: Rejuvra XL Herbicide may be tank mixed with other herbicides that are registered for the same use sites.
Invasive plant species: Rejuvra XL Herbicide may be used as a component of integrated vegetation management programs aimed at controlling common crupina, Iberian starthistle, South African ragwort and yellow starthistle.
Regional restrictions for use: There are no regional restrictions for Rejuvra XL Herbicide.

Table 16b Acceptable Pest Claims for Rejuvra XL Herbicide

Weed species	45 g a.i./ha or 85 g product/ha	90 g a.i./ha or 170 g product/ha
Balsam poplar	Suppression	12 month control
Black poplar	Control	
Bluebur	Control	
Buttercup, giant	Season-long control	12 month control
Canada goldenrod	Season-long control	
Canada thistle	12 month control	
Cinquefoil, Norwegian	Season-long control	
Common tansy	Control	
Common yarrow	Control	
Cow cockle	Control	
Dandelion	12 month control	
Knapweed, diffuse	Suppression	Control
Knapweed, Russian	–	Suppression
Knapweed, spotted	Suppression	12 month control
Kochia	Control (not including ALS-resistant)	Suppression of ALS-resistant biotypes
Lady’s-thumb	Control	
Leafy spurge	12 month suppression	12 month control
Orange hawkweed	12 month control	
Ox-eye daisy	12 month control	
Pasture sage	Suppression	12 month control
Redroot pigweed	Control	
Russian thistle	Control	

Weed species	45 g a.i./ha or 85 g product/ha	90 g a.i./ha or 170 g product/ha
Scentless chamomile	Control	
Annual sow thistle	Suppression	
Perennial sow thistle	Suppression	
Toadflax	Suppression	
Trembling aspen	12 month control	
Western snowberry	12 month control	
White cockle	12 month control	
Wild rose	Season-long control	12 month suppression
Willow, ditchbank	–	12 month suppression
Willow, sandbar	–	12 month suppression
Yellow starthistle	Control	

Where there is no claim indicated for the 90 g a.i./ha rate, the claim is the same as for the 45 g a.i./ha rate.

Appendix II Supplemental Maximum Residue Limit Information—International Situation and Trade Implications

Aminocyclopyrachlor is a new active ingredient in Canada. Both aminocyclopyrachlor (acid) and aminocyclopyrachlor methyl ester active ingredients are registered in the United States for non food and feed use. No MRLs on food, feed or animal commodities have been promulgated at this point (40 CFR Part 180).

Currently, there are no Codex MRLs established for aminocyclopyrachlor.

References

A. List of Studies/Information Submitted by Registrant

1.0 Chemistry

PMRA Document Number	Reference
1998574	2010, Aminocyclopyrachlor Technical Part 2.1 2.4 (Chemistry), DACO: 2.1,2.2,2.3,2.3.1,2.4
1998575	2010, Technical Grade Aminocyclopyrachlor (DPX-MAT28) Manufacturing Description and Formation of Impurities, DACO: 2.11.1,2.11.2,2.11.3,2.11.4
1998576	2010, Technical Grade Aminocyclopyrachlor (DPX-MAT28) Manufacturing Description and Formation of Impurities, DACO: 2.11.1,2.11.2,2.11.3,2.11.4 CBI
1998577	2010, Aminocyclopyrachlor (DPX-MAT28) identity, composition, and certified limits, DACO: 2.12.1
1998578	2010, Aminocyclopyrachlor (DPX-MAT28) identity, composition, and certified limits, DACO: 2.12.1 CBI
1998579	2010, Description and validation of the analytical method for determination of impurities in technical grade aminocyclopyrachlor (DPX-MAT28), DACO: 2.13.1
1998580	2010, Description and validation of the analytical method for determination of impurities in technical grade aminocyclopyrachlor (DPX-MAT28), DACO: 2.13.1 CBI
1998581	2008, Determination of aminocyclopyrachlor (DPX-MAT28) in technical grade aminocyclopyrachlor, DACO: 2.13.1,8.6
1998582	2008, Validation of the analytical method for determination of aminocyclopyrachlor (DPX-MAT28) in technical grade aminocyclopyrachlor, DACO: 2.13.1,8.6
1998583	2008, Validation of the analytical method for determination of aminocyclopyrachlor (DPX-MAT28) in technical grade aminocyclopyrachlor, DACO: 2.13.1,8.6 CBI
1998592	2007, DPX-MAT28: Laboratory study of dissociation constants in water, DACO: 2.14.10
1998593	2007, DPX-MAT28: Laboratory study of n-octanol / water partition coefficient, DACO: 2.14.11
1998594	2007, DPX-MAT28: Laboratory study of UV-VIS absorption spectrum and molar absorptivity, DACO: 2.14.12
1998595	2007, DPX-MAT28: Stability to normal and elevated temperatures, metals, and metal ions, DACO: 2.14.13
1998596	2008, DPX-MAT28: Long-term storage stability and corrosion characteristics, DACO: 2.14.14

PMRA Document Number	Reference
1998597	2007, DPX-MAT28: Laboratory study of water solubility, DACO: 2.14.7
1998598	2007, DPX-MAT28: Solubility in organic solvents, DACO: 2.14.8
1998599	2007, DPX-MAT28: Laboratory study of vapour pressure, DACO: 2.14.9
1998601	2008, DPX-MAT28: Volatility, calculation of Henrys law constant, DACO: 2.16
1998602	2007, DPX-MAT28: Laboratory study of pH, DACO: 2.16
1998603	2007, DPX-MAT28 (PAI): Spectra (mass spectrum, infrared spectrum, and NMR), DACO: 2.16
1998605	2007, DPX-MAT28: Laboratory study of explosive and oxidizing properties, flammability of solids and the relative self-ignition (autoflammability) temperature, DACO: 2.16
1998606	2008, Photochemical oxidative degradation of DPX-MAT28, DACO: 2.16
1998607	2008, Calculated theoretical lifetime for DPX-MAT28 in the top layer of aqueous systems, DACO: 2.16
1998608	2007, DPX-MAT28: Laboratory Study of Physiochemical Properties For A. Color B. Odor C. Physical State D. Melting Point E. Boiling Point/Decomposition F. Relative Density G. Bulk Density, DACO: 2.14.1, 2.14.2, 2.14.3, 2.14.4, 2.14.5, 2.14.6, 2.5, 2.6, 2.7, 2.8, 2.9
2121755	2008, Description and Validation of the Analytical Methods for Determination of Impurities in Technical Grade Aminocyclopyrachlor (DPX-MAT28), DACO: 2.13.1 CBI
2121756	2008, Description and Validation of the Analytical Methods for Determination of Impurities in Technical Grade Aminocyclopyrachlor (DPX-MAT28), DACO: 2.13.1
2146350	2011, Batch Analysis of Aminocyclopyrachlor (DPX-MAT28) Technical, DACO: 2.13.3 CBI
2146352	2011, Batch Analysis of Aminocyclopyrachlor (DPX-MAT28) Technical, DACO: 2.13.3 CBI
2210677	2012, Aminocyclopyrachlor (DPX-MAT28) Identity, Composition, and Certified Limits, DACO: 2.13.3 CBI
2210678	2012, Aminocyclopyrachlor (DPX-MAT28) Identity, Composition, and Certified Limits, DACO: 2.13.3 CBI
2216366	2012, Aminocyclopyrachlor (DPX-MAT28) Identity, Composition, and Certified Limits, DACO: 2.13.3 CBI
2216367	2012, Aminocyclopyrachlor (DPX-MAT28) Identity, Composition, and Certified Limits, DACO: 2.13.3 CBI

PMRA Document Number	Reference
1998685	2008, Independent laboratory validation of analytical method DuPont-22043 for the determination of DPX-KJM44, DPX-MAT28, IN-LXT69 and IN-QFH57 in soil using LC-MS/MS, DACO: 8.2.2.1,8.2.2.2
1998686	2009, Analytical method for the determination of DPX-KJM44, DPX-MAT28, and metabolite in soil using LC/MS/MS, DACO: 8.2.2.1,8.2.2.2
1998687	2008, Analytical method for the determination of DPX-KJM44, DPX-MAT28, and metabolite in soil using LC/MS/MS, DACO: 8.2.2.1,8.2.2.2
1998688	2008, Analytical method for the determination of DPX-KJM44, DPX-MAT28, IN-LXT69, and IN-QFH57 in water using LC/MS/MS, DACO: 8.2.2.2,8.2.2.3
2256194	2012, Analytical Method for the Determination of IN-V0977, IN-YY905, and IN-Q3007 in Water by LC/MS/MS and GC/MS., DACO: 8.2.2.3
1998266	2010, DPX-MAT 28 Herbicide Part 3.1.1, 3.1.4, DACO: 3.1.1,3.1.2,3.1.3,3.1.4 CBI
1998267	2010, Product Identity and Composition of End-use Product Aminocyclopyrachlor (DPX-MAT28) 50SG, DACO: 3.2.1,3.2.2,3.3.1
1998268	2010, Product Identity and Composition of End-use Product Aminocyclopyrachlor (DPX-MAT28) 50SG, DACO: 3.2.1,3.2.2,3.3.1 CBI
1998269	2008, Determination of aminocyclopyrachlor (DPX-MAT28) in Aminocyclopyrachlor SG end-use product, DACO: 3.4.1
1998270	2008, DPX-MAT28 50SG water soluble granule formulation: Laboratory study of physical and chemical properties, DACO: 3.5.1,3.5.11,3.5.12,3.5.13,3.5.14,3.5.15,3.5.2,3.5.3, 3.5.6, 3.5.7, 3.5.8,3.5.9,3.7
1998271	2009, DPX-MAT28 50SG water soluble granule formulation: Laboratory study of storage stability and corrosion characteristics, DACO: 3.5.10
1998272	2010, DPX-MAT 28 Herbicide Part 3.5.4-3.5.5, DACO: 3.5.4,3.5.5
2121776	2008, Validation Of The Analytical Method For Determination of Aminocyclopyrachlor Methyl (DPX KJM44), Aminocyclopyrachlor (DPX MAT28), Imazapyr (DPX A7586), Chlorsulfuron (DPX W4189), Metsulfuron Methyl (DPX T6376), And Sulfometuron Methyl PX T5648) In DPX Q6H73 WG, A Paste-Extruded Blend, Aminocyclopyrachlor Methyl (DPX-KMJ44) Water Dispersible Granule Formulations (WG), Aminocyclopyrachlor (DPX MAT28) Water Soluble Granule Formulations (SG), Aminocyclopyrachlor (DPX-MAT28) Soluble Concentrate Formulations (SL) And Other End Use Products, DACO: 3.4.1
1998390	2010, DPX-Q2K06-20101217-DACO 3.1 - 3.2, DACO: 3.1,3.1.1,3.1.2,3.1.3,3.1.4,3.2, 3.2.1, 3.2.2,3.2.3 CBI
1998391	2009, Aminocyclopyrachlor (DPZ-MAT28) 50SG/Chlorsulfuron 75WG (39.48/15.77% ai content), Blend of Water-Dispersable Granules Formulations (DPX-Q2K06):Laboratory Study of Physical and Chemical Properties, DACO:

PMRA Document Number	Reference
	3.5.10,3.5.11,3.5.12,3.5.13,3.5.14,3.5.15,3.5
2121952	2010, Aminocyclopyrachlor (DPX-MAT28) 50 SG/CHLORSULFURON 75 WG (39.48/15.77% AI Content) Blend of Water-Dispersible Granule Formulations (DPX-Q2K06): Laboratory Study of Storage Stability And Corrosion Characteristics, DACO: 3.5.10,3.5.14
1998410	2009, Determination of Metsulfuron Methyl (DPZ-T6376) and Aminocyclopyrachlor (DPX-MAT28) in DPX-Q2K13 WG End-use Product:Aminocyclopyrachlor 50SG/Metsulfuron Methyl 60 WG (DPX-Q2K13), A Blend of Extruded Granules (39.5% + 12.6% Active), DACO: 3.3.1,3.4 CBI
1998439	2010, Part 3.1- 3.2 (Chemistry) , DACO: 3.1,3.1.1,3.1.2,3.1.3,3.1.4,3.2,3.2.1,3.2.2 CBI
1998441	2009, Aminocyclopyrachlor (DPX-MAT28) 50 SG/Meusulfuron Methyl 60 WG (39.48% /12.62% ai content) Blend of Water Disperible Granule Formulations (DPX-Q2K13): Laboratory Study of Physical and Chemical Properties, DACO: 3.5.10,3.5.11,3.5.12,3.5.13,3.5.14,
2121800	2011, Aminocyclopyrachlor (DPX-MAT28) 50SG/ Metsulfuron Methyl 60 WG (39.48/12.62% AI Content) Blend of Water Dispersible Granule Formulations (DPX-Q2K13): Laboratory Study of Storage Stability And Corrosion Characteristics, DACO: 3.5.10,3.5.14
1998452	2010, Aminocyclopyrachlor 50SG/Metsulfuron Methyl 60WG (35.3/17.64% AI Content) Blend of Water-Dispersible Granule Formulations (DPX-RLC93): Laboratory Study of Physical And Chemical Properties, DACO: 3.5.10,3.5.11,3.5.12,3.5.13,3.5.14,3.5.15,3.5.2,3.5.4,
1998472	2010, Part 3.1 - 3.2 (Chemistry) , DACO: 3.1,3.1.1,3.1.2,3.1.3,3.1.4,3.2,3.2.1,3.2.2, 3.2.3
2121842	2011, Aminocyclopyrachlor 50SG/ Metsulfuron Methyl 60WG (35.3/17.64% AI Content) Blend of Water-Dispersible Granule Formulations (DPX-RLC93): Laboratory Study of Storage Stability And Corrosion Characteristics, DACO: 3.5.10,3.5.14
2256192	2012, Validation Of The Analytical Method For Determination Of Aminocyclopyrachlor (DPX-MAT28), Triclopyr (DPX-EV323), Chlorsulfuron (DPX-W4189), Metsulfuron Methyl (DPX-T6376), Hexazinone (DPX-A3674) and Diuron (DPX-14740) in Formulated Products DPX-RRW96, DPX-RYR68, DPX-Q2K06, DPX-Q2K13 And DPX-RLC93, DACO: 3.4.1
2256193	2012, Validation Of The Analytical Method For Determination Of Aminocyclopyrachlor (DPX-MAT28), Triclopyr (DPX-EV323), Chlorsulfuron (DPX-W4189), Metsulfuron Methyl (DPX-T6376), Hexazinone (DPX-A3674) and Diuron (DPX-14740) in Formulated Products DPX-RRW96, DPX-RYR68, DPX-

PMRA Document Number	Reference
	Q2K06, DPX-Q2K13 And DPX-RLC93, DACO: 3.4.1

2.0 Human and Animal Health

PMRA Document Number	Reference
1998609	2007, DPX-MAT28 Technical: Acute oral toxicity study in rats - up-and-down procedure, DACO: 4.2.1
1998610	2007, DPX-MAT28 Technical: Acute dermal toxicity study in rats, DACO: 4.2.2
1998611	2007, DPX-MAT28 Technical: Inhalation median lethal concentration (LC_{50}) study in rats, DACO: 4.2.3
1998612	2007, DPX-MAT28 Technical: Acute eye irritation study in rabbits, DACO: 4.2.4
1998613	2007, DPX-MAT28 Technical: Acute dermal irritation study in rabbits, DACO: 4.2.5
1998614	2007, DPX-MAT28 Technical: Local lymph node assay (LLNA) in mice, DACO: 4.2.6
1998615	2008, DPX-MAT28 technical: Subchronic toxicity 90 day feeding study in mice, DACO: 4.3.1
1998618	2008, DPX-MAT28 Technical: Subchronic toxicity 90-day feeding study in rats, DACO: 4.3.1,4.5.13
1998624	2008, DPX-MAT28 Technical: Subchronic toxicity 90-day feeding study in dogs, DACO: 4.3.2
1998629	2008, DPX-MAT28 Technical: Dermal toxicity study (28 day repeat dermal application study in rats), DACO: 4.3.5
1998631	2008, DPX MAT28 Technical: 28-Day immunotoxicity feeding study in male mice, DACO: 4.3.8
1998633	2008, DPX MAT28 Technical: 28-Day immunotoxicity feeding study in male rats, DACO: 4.3.8
1998634	2010, DPX-MAT28 technical: Oncogenicity 18-month feeding study in mice, DACO: 4.4.1,4.4.2,4.4.4
1998635	2010, DPX-MAT28 technical: Oncogenicity 18-month feeding study in mice, DACO: 4.4.1,4.4.2,4.4.4

PMRA Document Number	Reference
1998644	2010, DPX-MAT28 Technical: Combined Chronic Toxicity/Oncogenicity 2-Year Feeding Study in Rats, DACO: 4.4.1,4.4.3,4.4.4
1998659	2010, DPX-MAT28 technical: Chronic oral toxicity one-year feeding study in Beagle dogs, DACO: 4.4.5
1998662	2008, DPX-MAT28 Technical: Multi-generation reproduction study in rats, DACO: 4.5.1
1998669	2009, Oral (gavage) acute neurotoxicity study of DPX-MAT28-009 in rats, DACO: 4.5.12
1998671	2008, DPX-MAT28 technical: Developmental toxicity study in rats, DACO: 4.5.2
1998673	2008, A prenatal developmental toxicity study of DPX-MAT28 in rabbits, DACO: 4.5.3
1998675	2007, DPX-MAT28 Technical: Bacterial reverse mutation assay, DACO: 4.5.4
1998676	2007, DPX-MAT28 Technical: In vitro mammalian cell gene mutation test (CHO/HGPRT assay), DACO: 4.5.5
1998677	2007, DPX-MAT28 Technical: In vitro mammalian chromosome aberration test in human peripheral blood lymphocytes, DACO: 4.5.6
1998678	2007, DPX-MAT28 Technical: Mouse bone marrow erythrocyte micronucleus test, DACO: 4.5.7
1998679	2010, 14C-Aminocyclopyrachlor (DPX-MAT28): Absorption, distribution, metabolism, and elimination in the Sprague-Dawley rat, DACO: 4.5.9
1998680	2010, 14C-DPX-MAT28: Plasma pharmacokinetics and pilot material balance in male and female rats, DACO: 4.8
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B. Additional Information Considered

i) Published Information

1.0 Environment

RVD2008-08 Re-evaluation Decision – *Chlorsulfuron*. 15 Feb. 2008.
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ii) Unpublished Information

None considered.