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Registration Decision RD2014-30

Aminocyclopyrachlor

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Registration Decision for Aminocyclopyrachlor

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting 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 product has value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the consultation document[1] Proposed Registration Decision PRD2014-08, *Aminocyclopyrachlor*. This Registration Decision[2] describes this stage of the PMRA's regulatory process for aminocyclopyrachlor and summarizes the Agency's decision, the reasons for it. The PMRA received no comments on PRD2014-08. This decision is consistent with the proposed registration decision stated in PRD2014-08.

For more details on the information presented in this Registration Decision, please refer to the Proposed Registration Decision PRD2014-08, *Aminocyclopyrachlor* that contains a detailed evaluation of the information submitted in support of this registration.

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[3] 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 conditions of registration. The Act also requires that products have value[4] when used according to 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

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

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

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

4 "Value" as defined by subsection 2(1) of *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".

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.

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.

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 of PRD2014-08.

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 RVD2008-08, *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

Registered pesticide product labels 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 on the labels 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.

Other Information

The relevant test data on which the decision is based (as referenced in PRD2014-08, *Aminocyclopyrachlor)* are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

Any person may file a notice of objection[5] regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of the Health Canada's website (Request a Reconsideration of Decision) or contact the PMRA's Pest Management Information Service.

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