Registration Decision RD2014-04

Dichlorprop-P

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Registration Decision for Dichlorprop-P

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 A H Marks 2,4-DP-P 2EH Ester (Technical) and A H Marks 2,4-DP-P Technical Acid, Optica Trio, containing the technical grade active ingredients MCPA, dichlorprop-P and mecoprop-P, to control broadleaf weeds in wheat (spring, durum and winter), barley and oats and Estaprop XT Liquid Herbicide containing the technical grade active ingredients dichlorprop-P and 2,4-D (both present as 2-ethylhexyl ester) to control broadleaf weeds and brush in wheat (spring, durum and winter), barley and on industrial and non-crop land.

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 PRD2013-15, *Dichlorprop-P*. This Registration Decision[2] describes this stage of the PMRA's regulatory process for dichlorprop-P and summarizes the Agency's decision, the reasons for it. The PMRA received no comments on PRD2013-15. This decision is consistent with the proposed registration decision stated in PRD2013-15.

For more details on the information presented in this Registration Decision, please refer to PRD2013-15, which 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.

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".

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.

What is Dichlorprop-P?

Dichlorprop, also known as 2,4-DP, is currently registered in Canada. Dichlorprop exists in an equal ratio of two isomeric forms: R(+) and S(-). Only the R(+) isomer exhibits herbicidal properties, this isomer is known as Dichlorprop-P or 2,4-DP-P. Three forms; 2,4-DP-P acid, 2,4-DP-P dimethylamine salt (2,4-DP-P DMAS), and 2,4-DP-P ethylhexyl ester(2,4-DP-P EHE), are represented as Dichlorprop-P (2,4-DP-P) unless otherwise stated in this document.

Estaprop XT Liquid Herbicide contains the active ingredients dichlorprop-P ethylhexyl ester and 2,4-D ethylhexyl ester which both belong to the phenoxy herbicide family. Phenoxy herbicides are growth regulator herbicides, which mimic natural growth hormones, inducing rapid uncontrolled growth in broadleaf plants which eventually kills the plants. Estaprop XT Liquid Herbicide is a post-emergence herbicide. It is to be used on wheat (spring, durum and winter), barley and non-agricultural areas such as: roadsides, utility lines, railway rights-of-way, non-crop land for the control of a wide range of broadleaved weeds. It is also used for brush control.

The active ingredients in Optica Trio consist of dimethylamine salts of dichlorprop-P, MCPA and mecoprop-P which all belong to the phenoxy herbicide family. Optica Trio is a postemergence herbicide, applied to wheat (spring, durum and winter), barley, and oats, using ground application equipment, to control a range of broadleaved weeds.

Health Considerations

Can Approved Uses of Dichlorprop-P Affect Human Health?

2,4-dichlorprop-P is unlikely to affect health when used according to label directions.

Potential exposure to 2,4-DP-P may occur through the diet (food and water) or when handling and applying the product. 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 considerably higher than levels to which humans are normally exposed when 2,4-DP-P salt and 2,4-DP-P EHE products are used according to label directions.

Technical 2,4-DP-P acid and 2,4-DP-P EHE are moderately acutely toxic by the oral route, but are of low acute toxicity by the dermal and inhalation routes of exposure. The acid is extremely irritating to the rabbit eye affecting the cornea, while the eye irritation potential of the ester form of 2,4-DP-P was minimal. The difference in eye irritation potential might be related to the physical form of the acid (solid) and ester (liquid). The solid acid form might cause mechanical injury when instilled into the eye. Both the acid and ester forms of 2,4-DP-P were only slightly irritating to the rabbit skin. Although 2,4-DP-P is not a skin sensitizer, the ester is a skin sensitizer when tested in the guinea pig using the maximization method. Based on the acute toxicity data, the following label statements are displayed on the technical product labels: WARNING – POISON for both 2,4-DP-P acid and 2,4-DP-P EHE; **DANGER – CORROSIVE TO EYES** for 2,4-DP-P acid; and **POTENTIAL DERMAL SENSITIZER** for 2,4-DP-P EHE.

Optica Trio, an end-use product containing 2,4-DP-P, is slightly acutely toxic by the oral route, but is of low toxicity by the dermal and inhalation routes of exposure. The formulation is extremely irritating to the rabbit eye, but is only slightly irritating to the rabbit skin. Optica Trio is not a dermal sensitizer when tested in the guinea pig using the maximization protocol. Based on the acute toxicity data, the following label statements are displayed on the product labels: **CAUTION – POISON** and **DANGER – CORROSIVE TO EYES**.

The end-use product Estaprop XT Liquid Herbicide is moderately acutely toxic by the oral route, but is of low acute toxicity by the dermal and inhalation routes of exposure. The formulations are minimally irritating to the eye or skin and are not skin sensitizers. Based on the acute oral toxicity data, the following label statements are displayed on the product labels: **WARNING – POISON**.

In vivo and in vitro studies demonstrated that the 2,4-DP-P EHE is readily converted to 2,4-DP-P acid. Available bridging data indicated that the toxicity potential of 2,4-DP-P and 2,4-DP-P EHE is similar.

Both 2,4-DP-P acid and 2,4-DP-P EHE are not genotoxic, carcinogenic, neurotoxic, or teratogenic. The first signs of toxicity in animals given daily doses of 2,4-DP-P acid or 2,4-DP-P EHE over longer periods of time were effects on the liver, kidneys, and red blood cells (anemia). Observations in dogs at high doses also included diarrhoea and gastro-intestinal ulcers.

When 2,4-DP was given to pregnant rats, effects on reproduction and offspring survival were observed at doses that were also toxic to the maternal animals, indicating that the fetus is not more sensitive to 2,4-DP than adults are.

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

Residues in Water and Food

Dietary risks from food and water are not of concern

Aggregate dietary intake estimates, which include exposure from food plus drinking water, revealed that the general population and infants (the subpopulation which would ingest the most dichlorprop-P relative to body weight) are expected to be exposed to less than 3.3% of the acceptable daily intake. Similarly for the acute dietary exposure, the aggregate intake estimate (food plus water) for the general population is 9.2% of the acute reference dose and for the highest exposed sub-population, children 1-2 years old, the aggregate intake estimate is 14.7% of the acute reference dose. Based on these estimates, the acute and chronic dietary risk from dichlorprop-P is not of concern for all population subgroups. Dichlorprop-P is not carcinogenic; therefore, a cancer dietary risk assessment is not required.

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 using dichlorprop-P on wheat, barley and corn were acceptable. The MRLs for this active ingredient can be found in the Science Evaluation of the PRD2013-15.

Risks in Residential and Other Non-Occupational Environments

No residential and/or other non-occupational uses were requested. The product application directions on the label include statements to minimize spray drift. Thus, exposure health risks for bystanders in these environments are expected to be negligible.

Occupational Risks from Handling Optica Trio and Estaprop XT Liquid Herbicide

Occupational risks are not of concern when used according to the label directions, which include protective measures.

Farmers and commercial applicators when mixing, loading and applying as well as field workers re-entering freshly treated areas can come in direct contact with 2,4-DP-P residues on the skin or by inhalation. Therefore, the label specifies that anyone mixing/loading and applying must wear protective clothing and equipment. The label also requires that workers do not enter treated fields for 12 hours after application. These precautionary risk reduction measures are for all active ingredients in these products. Taking into consideration the Key Risk-Reduction Measures

specified in the section below, the number of applications and the expected exposure period for workers, the occupational risks are not a concern.

The occupational exposure and health risks from handling 2,4-D, MCPA and Mecoprop-P in the above end-use products are not of concern when these end-use products are used according to the label directions, which include protective measures, and as stipulated in the following Re-evaluation Decision Documents:

- Proposed Acceptability for Continuing Registration PACR2007-06, *Re-evaluation of the Agricultural, Forestry, Aquatic and Industrial Site Uses of (2,4-Dichlorophenoxy)acetic Acid [2,4-D];*
- Re-evaluation Decision document RVD2008-11, *(2,4-dichlorophenoxy) acetic acid [2,4-D]*;
- Proposed Re-evaluation Decision PRVD2007-01, *The agricultural, forestry and industrial uses of the herbicide (4-chloro-2-methylphenoxy) Acetic Acid (MCPA)*;
- Re-evaluation Decision RVD2008-20, *(4-chloro-2-methylphenoxy) Acetic Acid (MCPA)*; and
- Re-evaluation Decision RRD2004-09, *Mecoprop*.

Environmental Considerations

What Happens When Dichlorprop-P is Introduced into the Environment?

Dichlorprop-P is non-persistent with the main route of transformation in the terrestrial environment being biotransformation in soil. Dichlorprop-P is not expected to volatilise although it has the potential to leach to groundwater and in some circumstances may eventually flow into surface water. No major transformation products of dichlorprop-P were identified in aerobic soil laboratory studies. Dichlorprop-P can enter the aquatic environment through spray drift and run-off from treated fields. In aquatic systems, dichlorprop-P transforms rapidly via phototransformation and biotransformation to a number of minor transformation products.

The risk to the environment was assessed for the dichlorprop-P end-use products, Estaprop XT Liquid Herbicide and Optica Trio. In the terrestrial environment, Estaprop XT Liquid Herbicide and Optica Trio at the proposed application rate and use pattern may pose a risk to vascular plants, and predatory and parasitoid insects. These risks may be mitigated by applying spray buffer zones and other label statements. No risk was identified to earthworms, bees or birds.

In the aquatic environment Estaprop XT Liquid Herbicide and Optica Trio, at the proposed application rate and use pattern, are not expected to pose a risk to freshwater and marine aquatic invertebrates, fish and amphibians on an acute or chronic basis. A risk to freshwater algae and vascular plants was identified from exposure to runoff and drift. The risks identified from drift are mitigated by applying spray buffer zones and label statements. To reduce the potential risk from runoff, advisory statements are included on the label.

Value Considerations

What is the Value of Estaprop XT Liquid Herbicide?

Estaprop XT Liquid Herbicide controls a range of broadleaved weeds in wheat (spring, durum and winter), barley and non-agricultural areas such as: roadsides, utility lines, railway rights-of-way, and non-crop land. This product is also used for brush control. Estaprop XT Liquid Herbicide is compatible with integrated weed management practices, conservation tillage, and conventional crop production systems. Estaprop XT Liquid Herbicide is applied after weed emergence, allowing growers to better assess whether the herbicide is suitable for the particular weed species present.

What is the Value of Optica Trio?

Optica Trio provides effective control of a range of broadleaved weeds in wheat (spring, durum and winter), barley and oats. Optica Trio is compatible with integrated weed management practices, conservation tillage, and conventional crop production systems. Optica Trio is applied after weed emergence, allowing growers to better assess whether the herbicide is suitable for the particular weed species present.

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 being proposed on the label of Estaprop XT Liquid Herbicide and Optica Trio 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 2,4-DP-P, and other active ingredients in the end-use products, on the skin or through inhalation of spray mists, anyone mixing, loading and applying must wear the recommended PPE as noted below.

Technical 2,4-DP-P acid and 2,4-DP-P EHE

Based on the acute toxicity data, the following label statements are displayed on the technical product labels: **WARNING – POISON** for both 2,4-DP-P acid and 2,4-DP-P EHE; **DANGER – CORROSIVE TO EYES** for 2,4-DP-P acid; and **POTENTIAL DERMAL SENSITIZER** for 2,4-DP-P EHE.

For Estaprop XT Liquid Herbicide

Handling the concentrate (mixing/loading) for all scenarios: Mixers/loaders must wear coveralls over a long-sleeved shirt, long pants and chemical-resistant gloves, socks and shoes and protective eye wear (face shield or safety glasses). Rinse gloves before removal. When handling more than 660 L of this product per day workers must also use a closed system.

Application using ground or aerial equipment: Applicators must wear coveralls over a long sleeved shirt and long pants, socks and shoes. Chemical-resistant gloves must also be worn during clean-up and repair activities. Rinse gloves before removal. Gloves are not required during application when applicator is in an enclosed tractor or an enclosed airplane cockpit.

Application using handheld equipment: Applicators must wear coveralls over a long sleeved shirt, long pants and chemical-resistant gloves. Mixers/loaders/applicators using hand-held equipment must wear a respirator if they will be handling more than 12.5 L of this product per day. DO NOT handle more than 20 L of this product per day.

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

No human flaggers are permitted for aerial applications.

Re-entry is not permitted until 12 hours after application to all agricultural scenarios.

Based on the acute oral toxicity data, the following label statements are displayed on the product labels: **WARNING – POISON**.

For Optica Trio Broadleaf Herbicide

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

Re-entry is not permitted until 12 hours after application.

Based on the acute toxicity data, the following label statements are displayed on the product labels: **CAUTION – POISON** and **DANGER – CORROSIVE TO EYES**.

Environment

Mitigative measures are required to protect sensitive terrestrial and aquatic habitats from the use of dichlorprop-P. These mitigative measures include precautionary statements on the label regarding environmental hazards and the directions for use as well as appropriate buffer zones to protect sensitive habitats from spray drift.

Other Information

The relevant test data on which the decision is based (as referenced in PRD2013-15) 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.*