



Admire

The purpose of this Regulatory Note is to summarize the regulatory history of Admire, provide information on the current status and outline anticipated future directions.

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In January 1995, the Pest Management Regulatory Agency (PMRA) received a submission to register Admire for use on potatoes, tomatoes and apples. A similar submission was made to the Environmental Protection Agency in 1993; United States registration was granted in November 1994.

In response to representations from potato growers and their supporting agencies, a decision was made in concert with the manufacturer and other users to initially focus only on potatoes through a priority review. This decision recognized the critical pest management problems associated with Colorado Potato Beetle (CPB) resistance.

The outcome of this effort was a temporary registration for CPB use on potatoes in the 1995 season. In line with observations made by other regulatory bodies, the Agency had certain reservations with respect to the persistence and mobility of the active ingredient, imidacloprid, in soil. These views, based on information that was available at the time, were discussed with provincial officials and representatives of the production sector and their supporting agencies via conference calls, due to time constraints.

In brief, the KEY observations drawn from these data were:

1. persistence in soil of substantial portions of applied material;
2. potential for toxicity to aquatic invertebrates, parasites, predators and birds;
3. the opportunity for low-level residues in surface run-off water (e.g., tile drains);
4. the potential for leaching of freshly applied material (i.e., penetrating into ground water); and
5. the need for low-level residue rotational crop tolerances (in the U.S.) and plant-back restrictions.

In recognition of these considerations and as part of the Agency's interest in sustainable pest management:

1. Labelling was appropriately tailored:
 - the number of foliar applications was reduced from four to two;
 - a maximum of one soil application was allowed per year and could not be followed by foliar application within that same year;
 - buffer zones (15-30 m) were established between sensitive aquatic sites and areas where the product would be used;
 - application was limited to ground equipment, and aerial application was not allowed;
 - rotational crops could not be planted in areas treated with Admire within 12 months; and
 - applications were limited to Eastern Canada only.

The Health Evaluation Division of the PMRA has reviewed U.S. and European crop rotation data as a result of concerns about the persistence and the bioavailability of imidacloprid in soil. Low level residues in the following rotational crops: Swiss chard, wheat, beets, soybeans, peas and beans, indicate that low levels of this compound and its metabolites are persistent in soil for up to 300 days post-treatment. The studies did not extend beyond 300 days. It is anticipated that the establishment of

maximum residue limits (MRLs) to cover importation of crops resulting from the existing U.S. use patterns (data are presently being reviewed) will be sufficient to accommodate any residues in rotational crops resulting from the existing and proposed Canadian use patterns. U.S. crop residue data were generated and are under review by the Agency to cover the remaining rotation crops not directly covered by these MRLs (tolerances).

Data provided in the interim now allows the rotation to barley, oats and wheat 30 days after application of Admire 240F and to peas and beans 9 months after application of Admire 240F.

2. Certain terms and conditions, additional data requirements, were established in association with this temporary registration:

- aerobic, aquatic biotransformation studies;
- Canadian field studies on soil dissipation and accumulation;
- run-off modelling studies and ground water monitoring; and
- additional toxicity studies on aquatic invertebrates, earthworms, birds, algae, duckweed and beneficial insects.

Several of these studies (e.g., soil dissipation and ground water) are long-term and will not be completed for some time. However, a number of useful findings and observations have emerged including the following:

- The half-life of imidacloprid under anaerobic aquatic conditions indicates that it will be moderately persistent at low temperature. One major transformation product was formed: des-nitro imidacloprid (NTN 33823).
- The high solubility in water, the magnitude of the n-octanol/water partitioning coefficient, and the toxicity data for des-nitro imidacloprid (NTN 33823).
- The major transformation product and imidacloprid-urea (NTN 33519) indicate that both compounds will not bioaccumulate in aquatic organisms nor pose an appreciable risk to aquatic invertebrates.
- Water wells situated in and around treated fields in Ontario, Quebec and the Maritimes were monitored, and to date no imidacloprid was detected in ground water.
- Preliminary results of terrestrial field dissipation of imidacloprid in Canada indicate that the half-life of imidacloprid in bare soil ranged from 282 to 366 days, in soil with turf cover ranged from 224 to 257 days, and in soil planted with potatoes ranged from 266 to 457 days.
- Imidacloprid will not pose an appreciable risk to earthworms, terrestrial vascular plants, aquatic plants and algae, or fish.
- The possibility of low-level residues in surface run-off water (e.g., tile drains) was confirmed.

The fundamental areas of interest have not changed substantially in the interim. The challenge at hand seems to be one of properly describing and managing the inherent product characteristics. Consultation efforts over the last several months were undertaken as a contribution towards meeting that challenge.

In the interim, a significant use pattern has been registered in the U.S., including apples, eggplants, peppers, cole crops, lettuce, turf, greenhouse vegetables, ornamentals, etc. Many of these are of interest to Canadian producers in terms of having access to the same technology as, and a level playing field with, the U.S.

Performance on the CPB has been excellent and, with proper timing and/or application methods, additional testing has shown potential in sustainable pest management programs.

The Agency has been asked to consider a number of use expansions, many of them strongly advocated by producers and their supporting infrastructure, e.g.:

- greenhouse ornamentals and vegetables for control of thrips, aphids and whiteflies,
- Saskatoon berries for control of wooly aphid,
- turf, and
- foliar tomatoes.

The Agency will consider these types of use expansions in a sustainable pest management context based on assessment of a more complete environmental impact package, including the following submitted studies:

- laboratory studies of transformation and transport processes;
- runoff modelling with PRZM-2 and EXAMS for the estimation of imidacloprid runoff;
- field studies of transformation processes conducted in Belgium;
- preliminary results of terrestrial field dissipation of imidacloprid in Canada;
- toxicity of major transformation products NTN 33823 and NTN 33519;
- toxicity of imidacloprid to aquatic plants and algae;
- toxicity of imidacloprid to the mallard duck; and
- results from ground water monitoring studies in Ontario, Quebec, and the Maritime provinces.

It was in this context (i.e., sustainable pest management) that the Agency accepted, on a time-limited basis, early season use of Admire 240F in 1997 only, for the critical need pest: tentiform leafminer and the coincidental pests, white apple leaf hopper, aphids and mullein bug in apples.

Throughout the Agency's involvement with Admire, we have tried to maintain an appropriate balance between what we believe are legitimate reservations arising from product characteristics as indicated by the data available, and the Agency's commitment to support the competitiveness of agriculture, forestry, other resource sectors and manufacturing. The practical outcome has been a sustainable pest management approach reflected in:

1. Product labelling:

- limits on allowable treatments per year (number and rate);
- a requirement that mitigating measures such as buffer zones be established between areas of use and sensitive environments; and
- referencing alternative products and strategies in the interest of resistance management.

2. The development of Integrated Pest Management strategies in:

- urban landscapes (parks, golf courses and other green spaces, and providers of landscape services to homeowners and institutions);
- apple and peach orchards; and
- Colorado Potato Beetle, primarily in potatoes.

The goal of these projects is to develop a national strategy in partnership with users, provinces, extension experts, researchers, other government departments, pesticide manufacturers and other stakeholders, that is adaptable to regional situations and incorporates all tools currently available for use. Through this process, the product labelling for Admire can be reinforced by being incorporated into integrated pest management strategies presently being developed. Pest monitoring, as well as the development of resistance management strategies and the incorporation of alternative products, will be considered in the development of an Integrated Pest Management Program for each of these areas.

The Agency will maintain this judicious approach in the consideration of current use expansion requests. For example:

- The greenhouse use has limited potential for environmental impact and a special formulation or application technique to minimize the possible impact on parasites and predators.

The Agency is prepared to examine these use expansions to the imidacloprid use pattern where the following criteria are filled: uses in small/low environmental risk situations (e.g., greenhouses, Saskatoon berries, seed dressings) and critical need uses which are linked to sustainable pest management programs supported by provincial extension agencies. However, we expect to continue the current practice of time-limited registrations. This approach will allow appropriate access to the product while providing an opportunity for a scheduled review and reconsideration of the direction and adjustments that may be necessary over time.