Health Canada Santé Canada

Evaluation Report for Category B Subcategory 2.6 Application

Application Number: 2009-2328
Application: B.2.6 – New Combination of TGAI's
Product: Traxos Herbicide
Registration Number: 29855
Active ingredients (a.i.): Clodinafop-propargyl (CFP) + Pinoxaden (PRN)
PMRA Document Number : 1972356

Purpose of Application

The purpose of this application was to register a new product, Traxos Herbicide, containing the active ingredients Clodinafop-propargyl and Pinoxaden. Traxos Herbicide is to be used for post-emergent control of wild oats, volunteer (tame) oats, green foxtail, yellow foxtail, barnyard grass, Persian darnel, volunteer canary seed and proso millet in spring wheat and durum wheat.

Chemistry Assessment

Traxos Herbicide is formulated as an emulsifiable concentrate containing pinoxaden at a nominal concentration of 2.53% and clodinafop-propargyl at a nominal concentration of 2.53%. This end use product has a density of 0.99 g/mL and a pH of 5.9 (1% solution in water). The chemistry requirements for Traxos Herbicide are complete.

Health Assessments

Traxos Herbicide is of low acute oral, dermal and inhalation toxicity. It is minimally irritating to the eyes and moderately irritating to the skin of rabbits. It is a skin sensitizer in guinea pigs.

Residue data for clodinafop-propargyl and pinoxaden were submitted in support of the registration of the new end-use product. From a food residue exposure point of view, no changes in the magnitude of the residues in food and feed crops are expected and, therefore, no increase in dietary exposure is anticipated.

The uses of Traxos Herbicide should not result in an increase in potential occupational or bystander (reentry) exposure over currently registered uses of the active ingredients since the crops, application rates, number of applications, frequency of application and methods of application fall within the use pattern of currently registered products. Based on the acute toxicology of the Traxos Herbicide, specific statements regarding personal protective equipment are on the product label.

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Environmental Assessment

During the risk assessment of Traxos Herbicide, it was determined that potential risk to non-target aquatic organisms and terrestrial plants could occur as a result of spray drift at the application rates. The greatest risk to non-target aquatic organisms was from exposure to a formulant. The greatest risk to non-target terrestrial plants was from the active ingredient pinoxaden. Buffer zones of 1 to 15 metres are required to protect amphibian, freshwater, marine and terrestrial habitats. Environmental risk mitigation statements for run off have also been amended and updated to mitigate risk to non-target organisms.

Value Assessment

Data from 14 combined efficacy and crop tolerance trials conducted in Alberta, Saskatchewan, and Manitoba in 2008 were submitted to support the registration of Traxos Herbicide. Efficacy and crop safety of Traxos Herbicide applied alone and in combination with Benchmark Herbicide Tank Mix, Infinity Herbicide, Pulsar, and Buctril M were directly compared to that of the registered treatments of Horizon 240 EC + Score Adjuvant and Axial 100 EC Herbicide + Adigor in these trials. Control of wild oats, green foxtail, and Persian darnel was visually assessed 3 times during the growing season. The control of wild oats and Persian darnel following the application of Traxos Herbicide alone and in combination with Benchmark Herbicide Tank Mix, Infinity Herbicide, Pulsar, and Buctril M was acceptable and also comparable to that of Axial 100 EC + Adigor and Horizon 240 EC + Score Adjuvant. A reduction in green foxtail control was observed when Traxos Herbicide was tank mixed with Buctril M, Benchmark Herbicide Tank Mix, and Infinity Herbicide and this is consistent with the observations made when pinoxaden or clodinafop propargyl herbicide is in a tank mixture with some broadleaf herbicides (Traxos Herbicide contains the active ingredients of pinoxaden and clodinafop-propargyl).

The tolerance of five spring wheat varieties and one durum wheat variety to Traxos Herbicide applied alone and in combination with Benchmark Herbicide Tank Mix, Infinity Herbicide, Pulsar, and Buctril M was visually assessed 3 times during the growing season. Mean crop injury following the application of Traxos Herbicide alone and in combination with Benchmark Herbicide Tank Mix, Infinity Herbicide, Pulsar, and Buctril M was acceptable and comparable to that of Axial 100 EC + Adigor and Horizon 240 EC + Score Adjuvant.

Based on information made available, Traxos Herbicide was determined to be agronomically equivalent to that of the registered treatments of Horizon 240 EC + Score Adjuvant and Axial 100 EC Herbicide + Adigor as an alone treatment and when tank mixed with Buctril M, Curtail M, Trophy Herbicide Tank Mix, Prestige Herbicide Tank Mix, Infinity Herbicide, MCPA, Benchmark Herbicide Tank Mix, Pulsar, Mextrol 450 Liquid, Tilt 250 E Fungicide, Decis Flowable Insecticide, and Matador Insecticide.

Conclusion

The PMRA has conducted a review of the available information for this application and has concluded that Traxos Herbicide is acceptable for full registration.

References

1776276	2009, Acute Oral _TRAXOS_New Prroduct, DACO: 4.6.1
1776277	2009, Acute Dermal_TRAXOS_New Prroduct, DACO: 4.6.2
1776278	2009, Acute Inhalation_TRAXOS_New Prroduct, DACO: 4.6.3
1776279	2009, Eye Irritation_TRAXOS_New Prroduct, DACO: 4.6.4
1776280	2009, Dermal_Irritation_TRAXOS_New Prroduct, DACO: 4.6.5
1776281	2009, Dermal Sensitization_TRAXOS_New Prroduct, DACO: 4.6.6

714525	2004, Use Description Scenario for NOA-407855 100EC Herbicide (A12303C), DACO: 5.2
714527	2004, Pesticides Handlers Exposure Database (PHED) Assessment, DACO: 5.3

1776378	2009, Efficacy Abstract TSR_TRAXOS_New Prroduct, DACO: 10.2.3.3,10.3.2

1128880	1991, Determination of Residues of Metabolites CGA 153433 AND CGA193469 by Liquid Chromatography (Clodinafop-propargyl) DACO:3.5.10, 3.5.11, 3.5.12, 3.5.13, 3.5.14, 3.5.15, 3.5.2, 3.5.3, 3.5.4, 3.5.5, 3.5.6, 3.5.7, 3.5.8, 3.5.9, 7.2.1,7.2.2
1776265	2009, Product Identification_TRAXOS_New Product, DACO: 3.1,3.1.1,3.1.3,3.1.4 CBI
1776267	2009, Manufacturing Address_TRAXOS_New Product, DACO: 3.1.2 CBI
1776269	2009, Starting Material_TRAXOS_New Product, DACO: 3.2.1 CBI
1776270	2009, Formulation Process_TRAXOS_New Product, DACO: 3.2.2 CBI
1776271	2009, Formation of Impurities_TRAXOS_New Product, DACO: 3.2.3 CBI
1776272	2009, Certification of Limits_TRAXOS_New Product, DACO: 3.3.1 CBI
1776273	2009, Analytical Method SF-93/1 CGA 184927/NOV 407855EC (025/025) and S:CGA 185072 (006.25) by HPLC/Gas Chromatography., DACO: 3.4.1 CBI
1776274	2009, Chemical and Physical Properties_TRAXOS_New Product, DACO: 3.5, 3.5.1, 3.5.10, 3.5.11,3.5.12,3.5.13,3.5.14,3.5.15,3.5.2,3.5.3,3.5.4,3.5.5,3.5.6,3.5.7,3.5.8,3.5.9 CBI

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