

Evaluation Report for Category B, Subcategory 2.4, 3.12 Application

Application Number: 2007-4998
Application: New end-use products: proportion of formulants
New product labels: new site or host
Product: Stress Shield for Cereals and Soybeans
Registration Number(s): 29610
Active ingredients (a.i.): Imidacloprid
PMRA Document Number : 1863731

Purpose of Application

The purpose of this application was to register a new seed treatment product, Stress Shield for Cereals and Soybeans, for the control of certain insect pests on wheat, barley, oats, and soybeans.

Chemistry Assessment

Stress Shield for Cereals and Soybeans is formulated as a suspension containing imidacloprid at a nominal concentration of 480 g/L. This end-use product has a density of 1.184–1.203 g/mL and pH of 7.5–9.0. The chemistry requirements for Stress Shield for Cereals and Soybeans are complete.

Health Assessments

The formulation of the proposed product is identical to that of a currently registered product; therefore, no new toxicology assessment was conducted.

A health risk assessment has been conducted for the proposed product. It is not expected that exposure to workers and by-standers will increase over the exposure from currently registered products containing imidacloprid.

Previously reviewed residue data from field trials conducted for treated wheat and barley seed were reassessed in the framework of this application. Residue data from wheat and barley were extended to oats since they are representative crops of the cereal grains Crop Group 15. Supporting data was used as weight of evidence to support the registration on soybeans. Total residues of imidacloprid are not expected above the LOQ (0.05 ppm) in mature wheat, barley, oats from the proposed seed treatment at 10 to 30 g a.i./100 kg seed. Total residues of imidacloprid are not expected to exceed 0.1 ppm in soybeans when treated at 62.5 to 125 g a.i./100 kg seed. Furthermore, an increase in dietary exposure is not anticipated to any segment of the population, including infants, children, adults and seniors.

The existing MRL for imidacloprid on corn (0.05 ppm) will be replaced with an MRL of 0.05 ppm for the entire cereal grains crop group 15. Residues of imidacloprid, including metabolites containing the 6-chloropicolyl moiety in treated seeds of soybean will be covered by Part B, Division 15, subsection B.15.002 (1) of the FDAR; i.e. ≤ 0.1 ppm.

Environmental Assessment

The risk of environmental exposure to imidacloprid in the proposed product is not considered to be greater than that for currently registered products with the same active ingredient.

Value Assessment

Efficacy trials conducted in Ontario, Saskatchewan, British Columbia and Washington on wheat (spring, winter) and barley provide support for the use of Stress Shield for Cereals and Soybeans to provide early season protection against crop stand injury caused by wireworm (*Limonius* spp., *Agriotes* spp., *Ctenicera* spp.) at an application rate of 21-63 ml product/100 kg seed. No crop injury was observed on wheat and barley at application rates up to 63 ml product/100 kg seed. An extrapolation from the efficacy and crop tolerance results from wheat and barley can be extended to oats considering the similarity in seed size and plant structure between these crops. The rate range of 21-63 ml product/100 kg seed is supported for early season protection against crop stand injury caused by wireworm for wheat (spring, winter), barley and oats. No further data are required.

Efficacy trials conducted in Ontario, Wisconsin, Minnesota, Iowa and Nebraska on soybean provide support for the use of Stress Shield for Cereals and Soybeans to provide early season protection against soybean aphid, reduce early season defoliation caused by the over-wintering generation of bean leaf beetle and early season protection against crop stand injury caused by wireworm (*Limonius* spp.) and seedcorn maggot at an application rate range of 130-260 ml product/100 kg seed. No crop injury was observed on soybean at application rates up to 260 ml product/100 kg seed. The rate range of 130-260 ml product/100 kg seed is supported for use on soybean for early season protection against soybean aphid, for crop stand injury caused by wireworm and seedcorn maggot and to reduce early season defoliation caused by the over-wintering generation of bean leaf beetle. No further data are required.

Field trials were submitted to support an application to register tank mixes of Stress Shield for Cereals and Soybeans with Raxil T Flowable and Raxil MD Fungicides to treat wheat, barley and oat seeds and with Apron MAXX RTA Seed Treatment Fungicide to treat soybeans for diseases and insects. The data showed that there was no reduction in fungicide or insecticide efficacy when Raxil T Flowable and Raxil MD Fungicides were tank mixed with Stress Shield for Cereals and Soybeans and did not produce any negative effects when tank mixed. Specific diseases were not assessed in the soybean trials, but revealed no physical incompatibility or phytotoxic effects as a result of the tank-mix with Apron MAXX RTA and Stress Shield for Cereals and Soybeans. Raxil T Flowable and Raxil MD Fungicides are currently registered for use on wheat, barley and oats and Apron MAXX RTA is currently registered for use on soybeans at the rates proposed for tank mixing on the Stress Shield for cereals and soybeans label. Therefore the tank mixes are supported. No further data are required.

Conclusion

The PMRA conducted an evaluation of the subject application and found the information sufficient to support full registration of Stress Shield for Cereals and Soybeans.

References

PMRA Document Number: 1155804, 1155805

Reference: 1994, Method for the determination of total residues of imidacloprid in animal materials (Bayer method 0091 M001-reformatted), Data Numbering Code: 7.2.1

PMRA Document Number: 1155814

Reference: 1992, Method for the determination of total residues of imidacloprid in plant materials and drinking water (Bayer method 00200-reformatted), Data Numbering Code: 7.2.2, 7.2.3

PMRA Document Number: 1256346

Reference: 1998, Gaucho 480 FL, imidacloprid, Part 3, product chemistry studies - EP, Data Numbering Code: 3 Confidential Business Information

PMRA Document Number: 1295152

Reference: 1994, Method for the determination of total residues of imidacloprid in plant materials and beverages (Bayer method 00200 - reformatted), Data Numbering Code: 7.2.2, 7.2.3

PMRA Document Number: 1449830

Reference: 2007, Stress Shield® (imidacloprid), Canadian value package, Part 10 efficacy / value, Data Numbering Code: 10.1, 10.2, 10.2.1, 10.2.2, 10.2.3, 10.2.3.1, 10.2.3.3(c), 10.3, 10.3.1, 10.3.2(b), 10.4, 10.5, 10.5.1, 10.5.2, 10.5.3, 10.5.4

PMRA Document Number: 1449831

Reference: 2007, Efficacy summary tables for Stress Shield, Data Numbering Code: 10.1, 10.2, 10.2.1, 10.2.2, 10.2.3, 10.2.3.1, 10.2.3.3(c), 10.3, 10.3.1, 10.3.2(b), 10.4, 10.5, 10.5.1, 10.5.2, 10.5.3, 10.5.4

PMRA Document Number: 1449832

Reference: 2007, Efficacy summary tables for tank mixes, Data Numbering Code: 10.1, 10.2, 10.2.1, 10.2.2, 10.2.3, 10.2.3.1, 10.2.3.3(c), 10.3, 10.3.1, 10.3.2(b), 10.4, 10.5, 10.5.1, 10.5.2, 10.5.3, 10.5.4

PMRA Document Number: 1449833

Reference: 2007, Non-safety adverse effects summary tables for soybean, Data Numbering Code: 10.1, 10.2, 10.2.1, 10.2.2, 10.2.3, 10.2.3.1, 10.2.3.3(c), 10.2.3.3(d), 10.3, 10.3.1, 10.3.2(b), 10.4, 10.5, 10.5.1, 10.5.2, 10.5.3, 10.5.4

PMRA Document Number: 1449834

Reference: 2007, Non-safety adverse effects summary tables for tank mixes, Data Numbering Code: 10.1, 10.2, 10.2.1, 10.2.2, 10.2.3, 10.2.3.1, 10.2.3.3(c), 10.2.3.3(d), 10.3, 10.3.1, 10.3.2(b), 10.4, 10.5, 10.5.1, 10.5.2, 10.5.3, 10.5.4

PMRA Document Number: 1449840

Reference: 2006, Gaucho 480 SC – worker exposure during on-farm and commercial seed treatment of cereals, Data Numbering Code: 5.4

PMRA Document Number: 1449851, 1449853

Reference: 1997, Determination of residues of imidacloprid in barley, Data Numbering Code: 7.4.1

PMRA Document Number: 1449855, 1449856, 1449857

Reference: 1997, determination of residues of imidacloprid in wheat, Data Numbering Code: 7.4.1

PMRA Document Number: 1902557

Reference: 2010, Additional data, rationales and information to support the Stress Shield 480 label claim for white grub complex, seed-corn maggot and bean leaf beetle in cereals and soybeans, Data Numbering Code: 10.2.3.3(c)

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