

## Evaluation Report for Category B, Subcategory 2.4, 3.12 Application

**Application Number(s):** 2007-4993  
**Application:** New end-use product: proportion of formulators  
New product label: new site or host  
**Product(s):** Stress Shield for Cereals  
**Registration Number(s):** 29609  
**Active ingredients (a.i.):** Imidacloprid  
**PMRA Document Number:** 1863734

### Purpose of Application

Bayer CropScience has submitted an application to register a new end-use product, Stress Shield for Cereals, containing the active ingredient imidacloprid. Stress Shield for Cereals is proposed as a seed treatment for the control of certain insect pests on wheat, barley, and oats.

### Chemistry Assessment

Stress Shield for Cereals 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 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.  $\leq 0.1$  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 to provide early season protection against crop stand injury caused by wireworm (*Limoniusspp.*, *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 architecture between these crops. The rate range of 21-63 ml product/100kg seed is acceptable for early season protection against crop stand injury caused by wireworm for wheat (spring, winter), barley and oats. No further data are required.

Field trials were submitted to support an application to register tank mixes of Stress Shield for Cereals with Raxil T Flowable and Raxil MD Fungicides to treat wheat, barley and oat seeds for registered 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 did not produce any negative effects when tank mixed. Raxil T Flowable and Raxil MD Fungicides are currently registered for use on wheat, barley and oats at the rates proposed for tank mixing on the Stress Shield for Cereals label. Therefore the tank mixes are supported. No further data are required.

## Conclusion

The PMRA has conducted a critical evaluation of the subject application and has found the information sufficient to support the proposed use of Stress Shield for Cereals. As a result of this evaluation, the PMRA is proposing full registration of the subject product.

## References

- 1256346 End use chemistry-product ID, description of starting materials for Gaucho 480 flowable, formulation process, finished product specifications, validation, colour, physical state, odour, formulation type, container type, gravity, pH, oxidation/ reduction: chemical incompatibility, viscosity, storage stability, flammability, packaging material, voltage, [privacy information removed] DEC 23/97, JAN 13/98, NOV 28/97, DEC 3/97, NOV 27/97 (STR-10113;-10114;-10127;-10115;-10116;-10117;-10118;-10119;-10120;-10121;-10122;-10123;-10124;-10125;-10126) [GAUCHO 480 FL;SUB98-1458;REG26124;SUBMITTED NOV 15/98; VOL 1 OF 1 CHEMISTRY] [CBI]
- 1449830 2007, STRESS SHIELD (Imidacloprid), DACO: 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
- 1449831 2007, STRESS SHIELD (Imidacloprid), DACO: 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
- 1449832 2007, STRESS SHIELD (Imidacloprid), DACO: 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
- 1449833 2007, STRESS SHIELD (Imidacloprid), DACO: 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
- 1449834 2007, STRESS SHIELD (Imidacloprid), DACO: 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

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