

Evaluation Report for Category B
Subcategory 2.3 (Changes to EP Chemistry: Identity of Formulants) and
Subcategory 2.4-S-A-EP (Changes to EP Chemistry: Proportion of Formulants)
Application

Application Number: 2006-2585
Application: Evaluation Report for Category B, Subcategory 2.3 and 2.4
(Changes to Formulants)
Product: Cruiser 5FS Seed Treatment Insecticide
Registration Number: 27045
Active ingredients (a.i.): Thiamethoxam 46.6%
PMRA Document Number: 1427394

Background

Cruiser 5FS Seed Treatment Insecticide is used for the control of certain insect pests in wheat, barley, corn and soybeans. The active ingredient is thiamethoxam with a guarantee of 47.6%. This product contains the preservative 1,2- benzisothiazolin-3-one at 0.02%. It is to be applied once to seeds in commercial seed treatment facilities with closed transfer including closed mixing, loading, calibrating and closed treatment equipments only. The maximum application rate is 83 - 166 mL product / 100 kg seed (50 - 100 g a.i., or 0.125 - 0.25 mg per kernel).

Purpose of Application

The purpose of this application is to change the identity and proportion of formulants.

Chemistry Assessment

Cruiser 5FS Seed Treatment is a solution containing the active ingredient thiamethoxam at a nominal concentration of 47.6%. This product has a density of 1.31 g/mL and pH of 6-8. The chemistry requirements for Cruiser 5FS Seed Treatment are complete.

(TOX) Health Assessment

Thiamethoxam FS (600) is of low toxicity to rats via the oral ($LD_{50} > 5000$ mg/kg) and dermal ($LD_{50} > 5050$ mg/kg) routes. It is slightly toxic to rats via the inhalation ($LC_{50} > 1.57$ mg/L) route. It is non-irritating to the eye and skin of rabbits. It is not a dermal sensitizer in guinea pigs.

(OEAS) Health Assessment

The requested use of the proposed product, Cruiser 5FS Seed Treatment, is identical to the registered formulation and fits within the existing use patterns for thiamethoxam. A significant increase in exposure for mixer/loader, applicators or for workers handling the treated seed is not expected.

(FREAS) Health Assessment

To support the new formulation of Cruiser 5FS Seed Treatment Insecticide, no new residue data were submitted. Following the comparison of the new formulation to the original formulation of Cruiser 5FS Seed Treatment (PCP# 27045), there is no indication that any formulators will have an impact on the magnitude of the residues of thiamethoxam when the new formulation will be used according to the label, since the use directions are identical. Therefore, no increase in dietary exposure is anticipated.

Environmental Assessment

This application is for a formulation change which does not pose an increased risk to the environment. Therefore, additional environmental data were not required in support of the formulation change. This proposed use pattern does not affect the assessment of risk to non-target wildlife. Environmental concerns are mitigated on the existing label.

Value Assessment

Sixteen bridging trials were evaluated to determine if the efficacy and crop tolerance of a new formulation of Cruiser 5 FS (formulation A9765N) is equivalent to that of the registered formulation of Cruiser 5 FS (Reg. No. 27045) and Cruiser 350 FS (Reg. No. 27986). Of the 16 bridging studies that were evaluated, 3 of the studies were on wireworm in corn, 3 were on seedcorn maggot in dry edible beans, 3 on potato leafhopper in dry edible beans, 6 were on soybean aphid in soybeans, and 1 was on bean leaf beetle in soybeans. These trials support formulation and product equivalency.

Conclusions

The PMRA has completed an evaluation of the subject application and has found the information sufficient to support the formulation change for Cruiser 5FS Seed Treatment Insecticide.

Reference List

References List for Chemistry Assessment

7.1.1 Studies/Information Provided by Applicant/Registrant

1215405	2005, Product Identification, DACO: 3.1.1,3.1.2,3.1.3,3.1.4
1215406	2005, Starting Materials, DACO: 3.2.1
1215407	2005, Manufacturing Process, DACO: 3.2.2
1215408	2005, Certification of Limits, DACO: 3.3.1
1215409	2004, CGA 2933433 in 600FS Formulation (A9765N), SF-60/1, DACO: 3.4
1215410	2005, A9765N: Validation of Analytical Method of SF-60/1, T015924-04, DACO: 3.4.1
1215411	2005, Chemical and Physical Properties, DACO: 3.5
1215412	2005, Color, Physical State and Odor, T015916-04, DACO: 3.5.1,3.5.2,3.5.3
1215413	2004, A9765N: Density, T015918-04, DACO: 3.5.6
1215414	2004, A9765N: pH, T015917-04, DACO: 3.5.7
1215415	2004, A9765N: Oxidising Properties, HT04/333, DACO: 3.5.8
1215416	2004, A9765N: Viscosity, T015919-04, DACO: 3.5.9
1215417	2004, A9765N: Content of Active Ingredient(s) after Storage in Glass for 2 weeks at 54oC, T015920-04, DACO: 3.5.10
1215418	2004, A9765N: Flash Point, HT04/330, DACO: 3.5.11
1215419	2004, A9765N: Explosive Properties, HT04/331, DACO: 3.5.12
1215420	2004, A9765N: Corrosion Characteristics after Storage for 1 Year at 20oC, T015923-04, DACO: 3.5.14
1288515	2006, Cruiser Insecticide (EPA Registration Number: 100-941) Storage Stability at Ambient Temperature and Corrosion Characteristics of Thiamethoxam FS (600) (A9765N) (Addendum to MRID No.: 46412802), PC-06-114, MRID: 46412802, DACO: 3.5.10,3.5.14

Reference for (TOX) Health Assessment

PMRA 1351945 Thiamethoxam FS (600) (A9765N): Acute Oral Toxicity Study in Rats. STILLMEADOW, Inc., Sugarland, TX, USA. Laboratory report number 8545-04. Study report date: 7-October-2004. Applicant Report Number T016721-04. Unpublished. DACO 4.6.1.

PMRA 1351946. Thiamethoxam FS (600) (A9765N): Acute Dermal Toxicity Study in Rats. STILLMEADOW, Inc., Sugarland, TX, USA. Laboratory report number 8546-04. Study report date: 23-September-2004. Applicant Report Number T016722-04. Unpublished. DACO 4.6.2.

PMRA 1351947. Thiamethoxam FS (600) (A9765N): Acute Inhalation Toxicity Study in Rats. STILLMEADOW, Inc., Sugarland, TX, USA. Laboratory report number 8547-04. Study report date: 11-October-2004. Applicant Report Number T016723-04. Unpublished. DACO 4.6.3.

PMRA 1351948. Thiamethoxam FS (600) (A9765N): Acute Eye Irritation Study in Rabbits. STILLMEADOW, Inc., Sugarland, TX, USA. Laboratory report number 8548-04. Study report date: 21-September-2004. Applicant Report Number T016724-04. Unpublished. DACO 4.6.4.

PMRA 1351949. Thiamethoxam FS (600) (A9765N): Acute Dermal Irritation Study in Rabbits. STILLMEADOW, Inc., Sugarland, TX, USA. Laboratory report number 8549-04. Study report date: 7-October-2004. Applicant Report Number T016725-04. Unpublished. DACO 4.6.5.

PMRA 1351950. Thiamethoxam FS (600) (A9765N): Skin Sensitization Study in Guinea Pigs. STILLMEADOW, Inc., Sugarland, TX, USA. Laboratory report number 8550-04. Study report date: 7-October-2004. Applicant Report Number T016726-04. Unpublished. DACO 4.6.6.

Reference List for Value Assessment

A. List of Studies/Information Submitted by Applicant

PMRA 1251363 Small scale field efficacy studies. 23 pp. DACO 10.2.3.3. Received 28 March, 2006.

PMRA 1251364 Small scale field efficacy studies. 54 pp. DACO 10.2.3.3. Received 28 March, 2006.

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