

## Evaluation Report for Category A, Subcategory 1.3 Application

**Application Number:** 2007-5401  
**Application:** A.1.3 – Establishing Maximum Residue Limits  
**Product:** Tembotrione Technical Herbicide  
**Registration Number:** 29657  
**Active ingredients (a.i.):** Tembotrione  
**PMRA Document Number:** 2279503

### **Purpose of Application**

The purpose of this application was to establish maximum residue limits (MRLs) to cover residues of tembotrione and the metabolite M5 in/on field corn, sweet corn and popcorn following postemergence with tembotrione.

### **Dietary Exposure**

Based on corn metabolism studies, the residue definition for corn for risk assessment and enforcement purposes is tembotrione and the metabolite M5. An analytical method was provided which quantitates the residues of tembotrione and the metabolite M5 in corn commodities using liquid chromatography with mass spectroscopy (LC-MS/MS). Based on acceptable method validation and independent laboratory validation, the method was deemed adequate for data gathering and enforcement purposes.

To support the establishment of maximum residue limits (MRLs) on field corn, sweet corn and popcorn, data from residue trials were reviewed.

### **MRL Recommendations**

Based on the residue data, maximum residue limits (MRLs) to cover total residues of tembotrione and M5 in/on field corn, sweet corn and popcorn will be established as shown in Table 1.

**Table 1. Summary of Field Trial Data Used to Establish Maximum Residue Limit(s) (MRLs)**

Commodity	Application Method/ Total Application Rate	PHI (days)	Total Residues (ppm)		Recommended MRL
			Min	Max	
popcorn	Postemergence application/ 184-193 g a.i./ha	72-93	<0.02	<0.02	0.02
field corn	Postemergence application/ 180-195 g a.i./ha	76-112	<0.02	<0.025	0.02
sweet corn (K+CWHR)*	Postemergence application/ 182-190 g a.i./ha	44-46	<0.02	<0.035	0.04

\* kernel plus cob with husk removed.

The acute and chronic dietary exposure assessments have demonstrated that consumption of corn (field, sweet and pop) containing total residues of tembotrione at the recommended MRL levels, will not pose a concern to human health for any segment of the population, including infants, children and seniors.

### **Chemistry, Environmental, Value and Health Assessments**

For detailed assessments of the chemistry, environmental, value and other health aspects of tembotrione technical and related end-use products, please refer to ERC2012-02 - *Tembotrione*.

### **Conclusions**

Following the review of all available data, MRLs for the combined residues of tembotrione and the metabolite M5 at 0.02 ppm in/on field corn and popcorn, and at 0.04 ppm in/on sweet corn (K+CWHR) are recommended. Total residues of tembotrione in/on field corn, sweet corn and popcorn will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

## References

- 1270568 Metabolism of [phenyl-UL-14C]-AE 0172747 in corn (*Zea mays*) after treatment with an application rate of 100 g a.i./ha and 200 g a.i./ha in presence of safener isoxadifen-ethyl (AE F122006)
- 1270569 [Phenyl-U-14C]-AE 0172747: Absorption, distribution, metabolism and excretion following repeated oral administration to the laying hen
- 1270572 Metabolism of [cyclohexyl-UL-14C]-AE 0172747 in corn (*Zea mays*) after treatment with an application rate of 200 g a.i./ha in presence of safener isoxadifen-ethyl (AE F122006)
- 1270573 (14C)-AE 1417268:- Absorption, distribution, metabolism and excretion following repeated oral administration to the lactating cow
- 1270574 [Cyclohexyl-U-14C]-AE 0172747: Absorption, distribution, metabolism and excretion following repeated oral administration to the laying hen
- 1270575 [Phenyl-U-14C]-AE 0172747: Absorption, distribution, metabolism and excretion following repeated oral administration to the lactating cow
- 1270576 [Cyclohexyl-U-14C]-AE 0172747: Absorption, distribution, metabolism and excretion following repeated oral administration to the lactating cow
- 1312171 Development and Validation of a Residue Enforcement Method for the Determination of Residues of AE 0172474 and its Metabolites in/on Animal Material by HPLC-MS/MS. Demonstration of a LC/MS/MS Confirmatory Method.
- 1270577 ILV of the Bayer CropScience method no. 0096 for the determination of residues of AE 0172747 and its metabolite AE 1417268 in/on animal material by HPLC-MS/MS. Demonstration of a LC/MS/MS confirmatory method.
- 1270578 AE 0172747: Validation of analytical method AE/03/01 for AE 0172747 and its major metabolites AE 0456148 (M6), AE 1417268 (M5), and AE 1392936 (M2) in plant matrices using LC/MS/MS
- 1270581 Independent method validation of Bayer method numbers AE-003-A04-01 - AE 0172747: An analytical method for the determination of residues of AE 0172747 in beef tissues and milk matrices using LC/MS/MS
- 1270582 Independent laboratory validation of method 201059, AE 0172747: An analytical method for the determination of residues of AE 0172747 and its major metabolites AE 0456148, AE 1417268, and AE 1392936 in plant matrices using LC/MS/MS for AE 01
- 1270583 Independent laboratory validation of AE 0172747: An analytical method for the determination of residues of AE 0172747 in poultry tissues and egg matrices
- 1270584 Extraction efficiency of Bayer method AE/03/01 AE 0172747: Analytical method for the determination of residues of AE 0172747 and its metabolites AE 0456148, AE 1417268 and AE 1392936 in plants matrices using LC/MS/MS
- 1270585 Bayer method AE-004-A04-01 - AE 0172747 : An analytical method for the determination of residues AE 0172747 in poultry tissues and egg matrices using LC/MS/MS
- 1270586 AE 0172747 : An analytical method for the determination of residues of AE 0172747 in beef tissues and milk matrices using LC/MS/MS

- 1270587 AE 0172747: An analytical method for the determination of residues of AE 0172747 and its major metabolites AE 0456148, AE 1417268, and AE 1392936 in plant matrices using LC/MS/MS
- 1270588 [Cyclohexyl-UL14C]AE 0172747: Extraction efficiency of the residue analytical method for the determination of AE 0172747 in animal tissues and egg matrices using aged residues
- 1270589 Evaluation of AE 0172747 and relevant metabolites FDA multiresidue method (MRM) testing
- 1270591 Stability of AE 0172747, AE 0456148, AE 0968400, AE 1124336, AE 0941989 and AE 1392936 in soil during frozen storage, USA, 2003 (Reported through a maximum of 660 days storage)
- 1270592 Storage stability of AE 0172747, AE 0456148 (M6), AE 1417268 (M5), and AE 1392936 (M2) in turnip roots, mustard greens and yellow squash
- 1270593 Storage stability of AE 0172747, AE 0456148 (M6), AE 1417268 (M5) and AE 1392936 (M2) in corn grain, forage and fodder
- 1270600 AE 0172747: Magnitude of residues in popcorn resulting from foliar applications of AE 0172747 02 SC52 A1 under maximum proposed label specifications (2003)
- 1270601 AE 0172747: Magnitude of residues in sweet corn resulting from foliar application of AE 0172747 02 SC52 A1 under maximum proposed label specifications (2003)
- 1270602 AE 0172747 - Magnitude of residues in field corn resulting from foliar applications of AE 0172747 02 SC52 A1 under maximum proposed label specifications (2003)
- 1270605 AE 0172747: Magnitude of residues in processed wheat fractions when used as a rotational crop after field corn that has had exaggerated rate applications of AE 0172747 02 SC52 A1 (2003)
- 1270606 AE 0172747: Magnitude of residues in processed corn fractions following exaggerated rate applications of AE 0172747 02 SC52 A1 (2003) (including residue reduction information)
- 1427599 Isoxadifen-ethyl - Magnitude of the Residue in Sweet Corn and Popcorn (Amended Report)

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