1.0 EXECUTIVE SUMMARY

1.1 Study Design

An acute oral toxicity test was conducted with rats to determine the potential for Prothioconazole/Pydiflumetofen SC A23751C to produce toxicity from a single dose via the oral route.

An initial limit dose of 2000 mg/kg was administered to one healthy female rat by oral gavage. Due to the absence of mortality in this animal, four additional females received the same dose level, sequentially. Since three of five animals survived the limit test, no additional animals were tested. Females were selected for the test because they are frequently more sensitive to the toxicity of test compounds than males. All animals were observed for mortality, signs of gross toxicity, and behavioral changes at least once daily for 14 days after dosing or until death occurred. Body weights were recorded prior to administration (initial) and again on Day 7 and Day 14 (terminal) following dosing or after death. Necropsies were performed on all animals.

1.2 Results

At 2000 mg/kg dose level (5 animals), two animals died within one day of administration. Prior to death, these animals exhibited irregular respiration, piloerection, ataxia, and/or prone posture. Following administration, all surviving animals exhibited similar clinical signs. In addition, one survivor was hypoactive and two survivors exhibited diarrhea and/or reduced fecal volume. However, all surviving animals recovered by Day 3 and appeared active and healthy for the remainder of the 14-day observation period. Gross necropsy of the deceased animals revealed substance in the stomach and/or distention of the stomach and intestines. No gross abnormalities were noted for any of the surviving animals during necropsy at the conclusion of the 14-day observation period.

1.3 Conclusion

Under the conditions of this study, the acute oral median lethal dose, LD_{50} of Prothioconazole/Pydiflumetofen SC A23751C is greater than 2000 mg/kg of body weight in female rats.