

Evaluation Report for Category B, Subcategory 4.1 Application

Application Number: 2003-1308

Application: category B, subcategory: 4.1 **Product:** Thiamethoxam Technical Insecticide

Registration Number: 26665

Active ingredients (a.i.): Thiamethoxam (98%)

PMRA Document Number: 1425268

Background

Thiamethoxam technical grade active ingredient, "Thiamethoxam Technical Insecticide" (Reg. No. 26665) was first registered in 2001. At the time of the original evaluation and registration, it was determined that a developmental neurotoxicity study was required as a condition of the registration for the use of this active ingredient as a seed treatment. The PMRA has completed an evaluation of the developmental neurotoxicity study under the subject application and has determined that the study is acceptable and the data requirements to support the registration of thiamethoxam technical insecticide for seed treatment are complete. However, a subsequent petition for a major expansion of use (submission 2004-1936 for foliar application) was received prior to the conclusion of this evaluation. During the review of submission 2004-1936 additional data requirements were identified to more fully characterize the environmental risk assessment for Thiamethoxam Technical Insecticide in the context of the proposed use expansion.

Purpose of Application

The purpose of this application is to convert the temporary registration of the Thiamethoxam Technical Insecticide to a full registration. The company provided the developmental neurotoxicity study which was required for conversion of the seed use of thiamethoxam technical to full registration.

Chemistry Assessment

A chemistry assessment was not required as there was no change to product chemistry.

Health and Environmental Assessment

In the context of the seed use pattern, the health and environmental risk profile of Thiamethoxam Technical Insecticide was not altered from that of the original registration. However, additional toxicology data were submitted under submission # 2004-1936 which may serve to update the risk assessment for Thiamethoxam Technical Insecticide in the context of the expansion of use to include foliar application.



Value assessment

A value assessment is not required for technical grade active ingredient products.

Conclusions

While the outstanding data requirements for the seed use of Thiamethoxam Technical Insecticide have been addressed, the registration status of the subject product remains conditional contigent on fulfillment of the additional information required to address the use expansion to include foliar use. These additional information requirements are those resulting from the review of the use expansion under submission # 2004-1936.

References

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