Health Canada Santé Canada

Section 12 Notice **Additional Information Required to Fulfill the Terms and Conditions for Conditional Registration**

Product Name: **SPIRODICLOFEN TECHNICAL MITICIDE**
Registration Number: ***28050***
Application Number: ***2006-7111***
PMRA #: ***1438074***

During the conditional registration period which has been granted to December 31, 2007, the following information is to be generated and must be provided to the Pest Management Regulatory Agency by **December 1, 2007,** and must indicate the DACO numbers specified. A partial response to the outlined Terms and Conditions will not be accepted.

PART 2 **CHEMISTRY REQUIREMENTS FOR THE REGISTRATION OF A TECHNICAL GRADE OF ACTIVE INGREDIENT (TGAI) OR AN INTEGRATED SYSTEM PRODUCT**

DACO: **2.11.3**
Title: **Detailed Production Process**

Required DATA : **The applicant must provide the conditions used to produce the full scale TGAI including the yields of the intermediates formed in each step of the production process. This information can be provided at the same time as the submission of full scale batch data.**

DACO: **2.13.2**
Title: **Batch data**

Required DATA : **The applicant must submit data of 5 batches of the TGAI from a full scale production from Dormagen Germany which is the plant listed on the product specification form.**

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PART 4 TOXICOLOGY

DACO: 4.5.12
Title: Developmental Neurotoxicity Study (DNT)

Results from the DNT study provided evidence of developmental neurotoxicity, based on effects in brain morphometry, and learning and memory evaluations. Brain morphometry analyses were not conducted for low and mid dose animals, and therefore uncertainty remains regarding whether treatment-related findings also occurred for these dose groups.

Required Data: **In light of the treatment-related brain morphometric findings at the highest dose tested in the submitted DNT study, additional analyses of brain slices from the low and mid dose groups (postnatal days 21 and 75) is required. The applicant is strongly encouraged to contact the PMRA to discuss approaches for further investigating effects on the developing nervous system in the DNT study (e.g. Fluoro-Jade staining to investigate the presence of neuronal degeneration [Axt et al., 1994; Schmued et al., 1997; OECD, 2004]) prior to initiating the additional morphometric analyses.**

DACO: 4.8
Title: Other toxicology studies

Results from the acute toxicity studies suggest that the enol metabolite, BAJ 2510, is of higher toxicity than BAJ 2740 on an acute basis. Although it is unlikely that direct, repeated dosing with the enol metabolite could result in a different spectrum of toxic effects or effects at lower doses, based on the metabolism and mechanistic data provided, these possibilities cannot be ruled out.

Required Data: **Additional toxicology information is required to more fully characterize the toxicity following direct, repeated dosing with the enol metabolite, and the impact of this metabolite on the risk assessment. The applicant is encouraged to contact the PMRA to discuss protocols prior to initiating any additional studies.**