



Clothianidin: Summary of findings of new time dependant sorption study, preliminary groundwater and soil risk assessment of new metabolite pattern and workplan outline

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During the performance of a new study (5.1.2.e WOO 2011 (M-405885-01-1)) to further investigate the time dependant sorption behaviour of clothianidin in soil Bayer CropScience (BCS) has identified some differences to the previously described route of degradation of clothianidin in aerobic soil.

The new study was performed with [¹⁴C] – clothianidin as a route and rate of degradation study with analysis of all extracts. As a result of this analysis the following significant findings were noted:

- Identification of a new soil metabolite TZFA (N-[(2-chloro-1,3-thiazol-5-yl)methyl]-N'-methylimidofornamide) at amounts of up to 6.7% in one soil at day 35 and decreasing to the end of the study. The maximum in the three other soils was < 3%.
- Increase in the amount of TZMU (1-(2-chloro-1,3-thiazol-5-ylmethyl)-3-methyl-urea) formed, the maximum amount of TZMU increased to 10.6% on day 9 of the study in one soil. Maximum in the other soils was 5.9%. In the previous studies TZMU was detected at a maximum of < 5%.

The consequence of these noted differences is that the two metabolites TZFA and TZMU should be included in the groundwater risk assessment and PEC_{gw} simulations.

Additionally in the case of TZMU the impact on soil organisms should be considered.

Groundwater risk assessment:

Considering that neither compound was identified in the leachate of the lysimeter studies performed with clothianidin it is unlikely that either compound is a risk to groundwater.

Initial, preliminary estimations of the groundwater concentrations of TZMU and TZFA done for an EU GAP confirm the lysimeter results. The preliminary PEC_{gw} of TZMU and TZFA were substantially below the groundwater trigger, providing a fair margin of safety. These results

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strongly suggest that the concentration of the metabolites in groundwater would not trigger a relevance assessment.

For the metabolite TZMU some toxicological data was available during the Annex I inclusion of clothianidin where it was concluded that the compound is not genotoxic. The K_{oc} was also evaluated during Annex I inclusion and is available in the list of endpoints (mean K_{oc} 61.8 mL/g).

To confirm this initial assessment of the risk to groundwater and to enable the calculation of PEC_{gw} the following action plan has already been initiated:

Study type / title	Completion date	Study number	Comments
[Guanidine- ¹⁴ C]clothianidin: Time dependent sorption from four European field dissipation soils	2011-04-11	M-405885-01-1	In this study the new metabolite pattern has been detected (including the new metabolite TZFA)
[Imidoformamide- ¹⁴ C] BCS-CQ88479: Adsorption/desorption in five different soils	2011-04-21	M-407208-01-1	The new metabolite TZFA has been synthesized in ¹⁴ C labelled form to be used in this study. The study provides the K_{oc} value for TZFA.
Aerobic soil dissipation study of TZFA	November 2011	ongoing	The study provides the DT_{50} value for TZFA
Modelling of TZMU DT_{50} value (using information from the TDS study (available) and the TZFA dissipation study (ongoing))			The study provides the DT_{50} value for TZMU
Modelling of groundwater concentration (PEC_{gw}) of TZFA and TZMU	December 2011 (after availability of all study data)		

It is anticipated that the outcome of the action plan will be available before the end of 2011.



Soil risk assessment:

Although there is no specific ecotoxicity testing available for the metabolite TZMU there are several field studies available that demonstrate that under practical use conditions clothianidin has no impact on the earthworm population or organic matter degradation. As the metabolite TZMU, if formed under agricultural use conditions, would have been co-tested with the parent, it can be concluded that TZMU would also not have any impact on the earthworm population.

TZFA is present at < 10% and therefore, under current guidelines, no additional testing is required.

Sincerely,

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Global Regulatory Manager Insecticides