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Registration Decision

RD2017-15

# Saflufenacil

*(publié aussi en français)*

**15 September 2017**

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

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Canada 

ISSN: 1925-0932 (print)  
1925-0940 (online)

Catalogue number: H113-25/2017-15E (print version)  
H113-25/2017-15E-PDF (PDF version)

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## Registration Decision Statement<sup>1</sup> for Saflufenacil

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of saflufenacil technical, Kixor and the herbicide end-use product, Detail, containing the technical grade active ingredient saflufenacil, to control broadleaf weeds in non-cropland areas.

This decision is consistent with the Proposed Registration Decision PRD2017-07, *Saflufenacil*, which contains a detailed evaluation of the information submitted in support of this registration. The evaluation found that, under the approved conditions of use, the products have value and do not present an unacceptable risk to human health or the environment. See Appendix I for a summary of comments received during the consultation process as well as the PMRA's response to these comments.

### Other Information

The relevant test data on which the decision is based (as referenced in PRD2017-07, *Saflufenacil*, are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

Any person may file a notice of objection<sup>2</sup> regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of the Health Canada's website (Request a Reconsideration of Decision) or contact the PMRA's Pest Management Information Service.

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<sup>1</sup> "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

<sup>2</sup> As per subsection 35(1) of the *Pest Control Products Act*.



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## Appendix I    Comments and Responses

### 1. Comment

A Level 1 ground water exposure assessment was conducted by PMRA to derive EEC<sub>gw</sub> values for combined saflufenacil residues (saflufenacil + M800H01 + M800H02 + M800H07 + M800H08). The reported 90th percentile daily and yearly average EEC<sub>gw</sub> concentrations were 323 µg/L (see Table 3.3.2.1.2, page 17 of PRD2017-07).

The aerobic soil biotransformation half-life selected by PMRA for the modeling exercise was 3470 days, stated to be the maximum of three available values. The three values cited appear to come from Table 7, page 83 of the original review for the active ingredient, PRD2009-18 (30 December 2009).

Based on the current kinetic assessment SOP and using the current version of the PestDF kinetic fitting tool, representative half-lives of 532 days for the sandy loam soil, 715 days for the silty clay loam soil (Figure 1), and 722 days for the loamy sand soil are derived.

The longest of these values, 722 days, be used for the EEC<sub>gw</sub> calculations in PWC for the combined residues of saflufenacil (saflufenacil + M800H01 + M880H02 + M800H07 + M800H08). The value used in PRD2017-07 by PMRA, 3470 days, is not selected in a manner consistent with current procedures and is exceedingly conservative.

### Response 1

In this example, the IORE model fit is nearly identical to the SFO model fit, and both differ qualitatively from the DFOP fit. This can be seen in both the main plot and the residuals plots, which show that only the DFOP model fit follows the curve of the data. Because the IORE and SFO fits match each other but do not match the data, the default comparison between them used by xxDeg (PestDF) is not valid, and PMRA chose the one model which does match the data, the DFOP model. At the time these endpoints were calculated, the xxDeg package fit FOMC (rather than IORE) and produced a better fit, but resulted in a much larger representative half-life ( $T_R$ ) value of  $1.1 \times 10^{11}$  days (Figure 2; i.e., the FOMC  $T_R$  was calculated by multiplying the  $DT_{90}$  by  $\log 2 / \log 10$ ). Therefore, the lower value from DFOP was chosen with a  $T_R$  of 3470 d for water modelling.

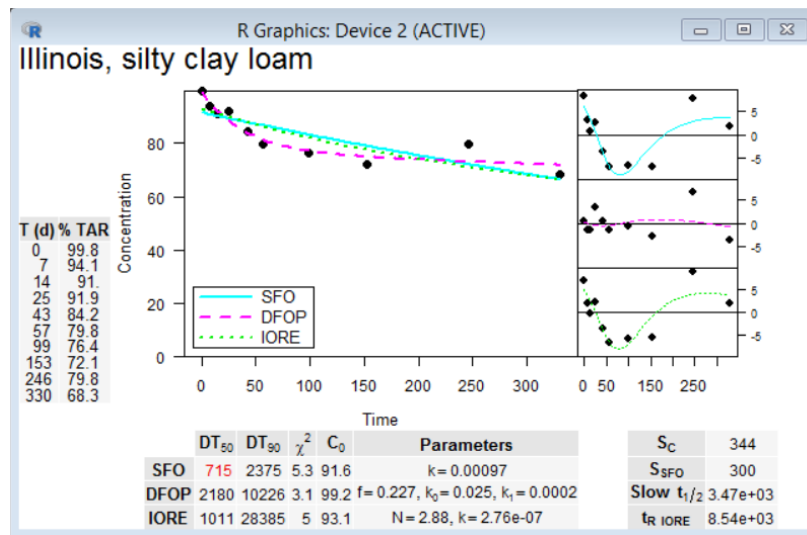


Figure 1: PestDF (xxDeg 0.8.13 in R 3.3.3) output (proposed by the applicant for PRD2017-07)

## aerobic soil metabolism (SFF+M01+M02+M07+M08)

DAT	Illinois
0	99.83
7	94.08
14	90.99
25	91.89
43	84.25
57	79.79
99	76.41
153	72.09
246	79.82
330	68.33

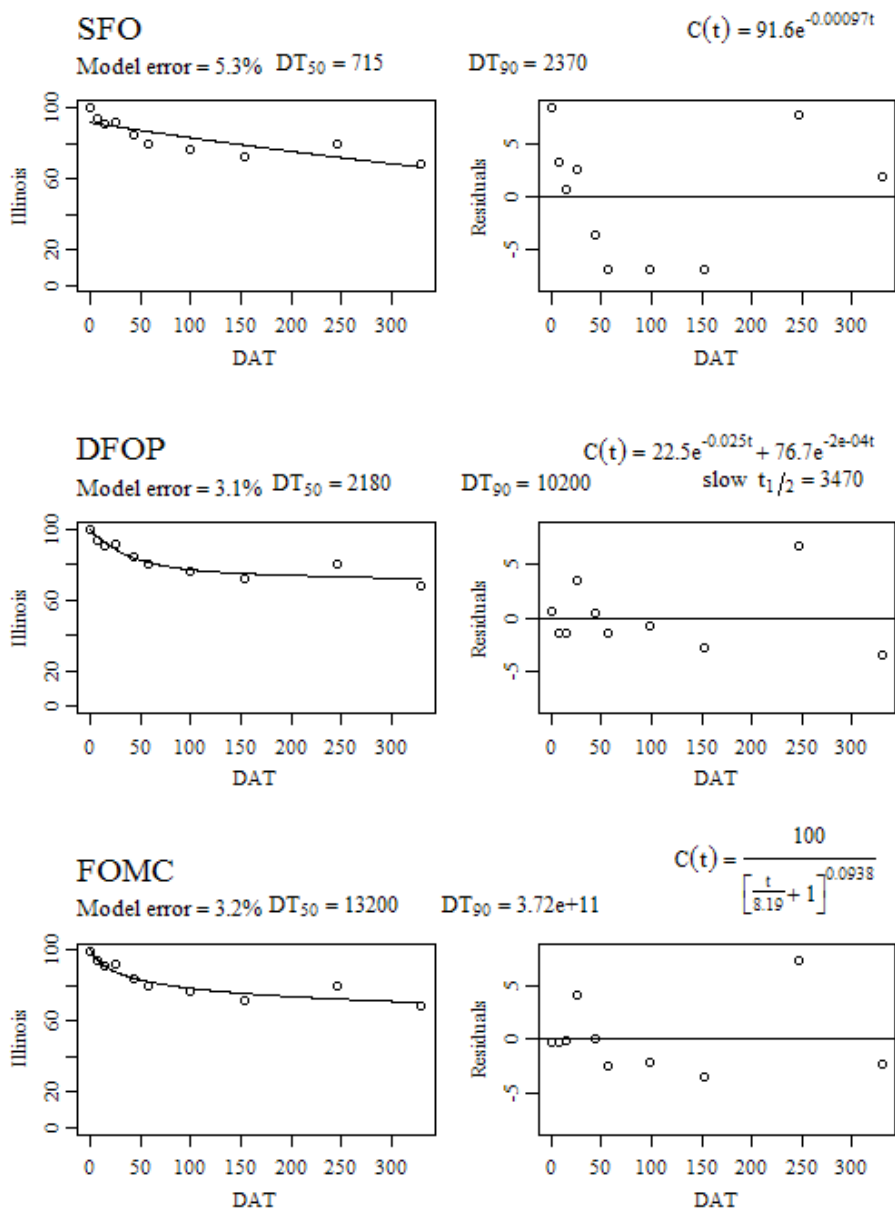


Figure 2: Same PestDF output with a representative  $t_{1/2}$  of 3470 d (used in PRD2009-18; EAD Water Modelling Input).