

A8207M

Fludioxonil 25 g/L FS

**NOTIFICATION OF AN ACTIVE
SUBSTANCE UNDER COMMISSION
REGULATION (EU) 844/2012**

**DOCUMENT L-CP, Section 9 Reference
List**

**FATE AND BEHAVIOUR IN THE
ENVIRONMENT**

Version history¹

Date	Data points containing amendments or additions and brief description	Document identifier and version number

¹ It is suggested that applicants adopt a similar approach to showing revisions and version history as outlined in SANCO/10180/2013 Chapter 4 How to revise an Assessment Report.

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- Art. 33 Justifications of steps taken to avoid animal testing and duplication of such testing
- Justification: There is no repetition of studies involving vertebrates. Animal studies were only performed where there were no data available to address an endpoint, no extrapolation to existing data possible or the available data were not done according to modern guidelines or because they were necessary to comply with regulatory requirements outside of EU28. The testing strategy takes into account methods compliant with the 3R concept for refinement, reduction and replacement of animal testing where applicable and acceptable.
- Art. 33 Reasons for necessity for submission of tests and study reports
- Reason: since this active substance was previously registered there have been changes to active substance endpoints and test, study and assessment guidelines; therefore where necessary in order to obtain re-approval new tests and study reports are provided.

Reference List, by Data Point**KCP Section 9, Fate and behaviour in the environment**

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner (SYN = Syngenta)
KCP 9.2.4.1 / 01	Klose A.	2016	Fludioxonil - A Leaching Assessment Using the PEARL 4.4.4, PELMO 5.5.3 and MACRO 5.5.4 Groundwater Models Following Seed Treatment Application to Spring and Winter Cereals Syngenta Dr Knoell Consult GmbH, Mannheim, Germany, 103705-8 Not GLP not published Syngenta File No CGA173506_11925 This is CONFIDENTIAL INFORMATION*	N	N	-	SYN

*Syngenta requests data confidentiality for these data. Disclosure of the information might undermine Syngenta's commercial interests by providing access to Syngenta specific know-how used to develop unique positions and approaches to risk assessment.

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Listing of Test and Study Reports and published Papers not submitted, by Author

KCP Section 9, Fate and behaviour in the environment

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None