Section A7.1.1.1.2
Annex Point IIA7.6.2.2

Phototransformation in water including identity of transformation products

4.4.3	k^c_p	The measured photolysis rate constant k^c_p for the test substance over the 13.8 day exposure was $0.7391 d^{-1}$ which is equivalent to a half life of 0.9 days. The rate constant over 1.8 days was also calculated to reduce the impact of the absorption by the photo-degradation products. This value was $0.7451\ d^{-1}$ which is also equivalent to a half-life of 0.9 days.
4.4.4	Kinetic order	First order
4.4.5	k^c_p / k^a_p	Not calculated
4.4.6	Reaction quantum yield (ϕ^c_E)	The quantum yield was calculated to be 1.57×10^{-4} (see Table A7.1.1.1.2-2)
4.4.7	k_{pE}	Not calculated
4.4.8	Half-life ($t_{1/2E}$)	The quantum yield was used to calculate the rate of photochemical degradation in water at different latitudes and seasons, using the GC Solar computer program. The results which are summarized in Table A7.1.1.1.2-4. For example, at 40° N latitude, the calculated half-life in river water at depths ranging from 0 – 30 cm was 1.8 to 11.2 days (depending upon the season and depth).
4.5	**Specification of the transformation products**	Several degradation products were observed (up to 18) and many were identified by co-chromatography with reference compounds. The chemical names of those identified and the maximum percent of parent compound are summarised in Table A7.1.1.1.2-3.

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	Guidelines: Directives 95/36/EEC and 94/37/EEC; SETAC (1995); US EPA OPPTS 835.2210 No relevant deviations from test guidelines. Method: The study meets the requirements of the SETAC guidance for aqueous photolysis issued in 1995 and the US EPA guidance OPPTS 835.2210. ^{14}C-labelled dinotefuran was irradiated with a xenon arc light source, continuously during 13.8 days under sterile conditions in aqueous buffer solution at pH 7 and 23-24°C. A control solution was treated in the same way as the irradiated solutions, except that it was kept in the dark. The quantum yield was calculated from the rate of degradation of dinotefuran measured by HPLC of samples taken at intervals and using an actonimeter. The quantum yield was then used to estimate the lifetime of the chemical in the aquatic environment.
5.2	**Results and discussion**	Using a buffer solution at pH 7, a rapid photodegradation of dinotefuran was observed. After 0.9 and 4.9 days of irradiation, 51.1% and 4.7% of the initial applied radioactivity remained, respectively. After 13.8 days of irradiation, dinotefuran was no longer detected. A half-life of 0.9 days was calculated using first-order kinetics, with up to 18 photo-products being detected. Dinotefuran samples kept in the dark were shown to be stable. The quantum yield of dinotefuran was determined to be 1.57×10^{-4} molecules degraded $photon^{-1}$ in buffer solution at pH 7, using the UV absorption data and the degradation kinetics. The rate of photochemical degradation in water at different latitudes and seasons was calculated using this value. The results are summarised in Table A7.1.1.1.2-4.

Section A7.1.1.1.2 Annex Point IIA7.6.2.2 Phototransformation in water including identity of transformation products

5.3 Conclusion The validity criteria can be considered as fulfilled as reference chemicals were studied using the same light source. Dinotefuran in aqueous solution was rapidly degraded by the light source with a half life of 0.9 days. Dinotefuran in the same conditions but in the dark was found to be stable.

5.3.1 Reliability 1

5.3.2 Deficiencies No

Table A7.1.1.1.2-1: Degradation of dinotefuran during irradiation. Mean concentrations used for calculation of half life.

Time (days)	Dinotefuran (mg/L)	Dinotefuran % applied
0.0	0.725	100.7
0.1	0.672	93.3
0.2	0.633	87.8
0.4	0.541	75.1
0.9	0.368	51.1
1.8	0.179	24.9
4.9	0.034	4.7
6.9	0.016	2.2
11.0	0.017	2.4
13.8	n.d.	n.d.

n.d. = not detected

Table A7.1.1.1.2-2: Calculation of Quantum Yield

Number of photo reacted test substance molecules in DT-50/100	1.85×10^{15} in 0.0093 days
Number of photoreacted actinometer molecules in 1200seconds (20 minutes)	4.668×10^{20} in 1200 seconds
Quantum yield of the actinometer	0.56 photo-reactions per absorbed photon
Photons absorbed by the actinometer	$4.668/0.56 = 8.3355 \times 10^{20}$ in 1200 seconds
Photons absorbed by the actinometer (corrected for partial absorption between 340 and 490nm)	1.595×10^{21} in 1200 seconds
Photons absorbed by the actinometer (corrected for time and area to be same as test substance experiment)	1.069×10^{21} in 0.0093 days
Quantum Yield	1.57×10^{-4}

Using the UV absorption data and the degradation kinetics, the quantum yield of dinotefuran was determined to be $\Phi = 1.57 \times 10^{-4}$ molecules degraded photon^{-1} in buffer solution at pH 7.

Table A7.1.1.1.2-3: Specification and amount of transformation products

Code Name	**CAS and/or IUPAC Chemical Name(s)**	**Mean amount [%] of parent compound measured at pH 7**
UF	1-methyl-3-(tetrahydro-3-furylmethyl)urea	Maximum 10.6% at 13.8 days
MG	1-methylguanidine	Maximum 10.2% at 1.8 days
DN-2-OH +DN-3-OH	1-(2-hydroxytetrahydro-3-furylmethyl)-3-methylguanidine (DN-2-OH) *and* 1-(3-hydroxytetrahydro-3-furylmethyl)-3-methylguanidine (DN-3-OH)	Maximum 28.1% at 13.8 days
BCDN	3-(methylamino)-9-oxa-2-aza-4-azoniabicyclo[4.3.0]non-3-ene	Maximum 16.1% at 1.8 days
M2	Not identified	Maximum 16.6% at 11 days : more than one component from chromatographic behaviour
DN	1-methyl-3-(tetrahydro-3-furylmethyl)guanidine	Maximum 7.4% at 11 days

Table A7.1.1.1.2-4: Calculation of theoretical half-life time at the surface of water in different latitudes and seasons from the quantum yield using GC-Solar

Theoretical lifetime (days) at the surface of water*	**Spring**	**Summer**	**Fall**	**Winter**
Latitude 30° N	1.97	1.70	2.91	4.34
Latitude 40° N	2.29	1.80	4.11	7.76
Latitude 50° N	2.83	1.97	6.93	18.60

*Conditions: Pure water close to the surface (0 – 5 mm), longitude 10°, terrestrial type of atmosphere, typical ephemeride and ozone values.

Table A7.1.1.1.2-5: Calculation of theoretical half-life time at various depths in typical river water (taken from River Rhine) at a latitude of 40° N from the quantum yield using GC-Solar

Theoretical lifetime (days) in river water*	**Spring**	**Summer**	**Fall**	**Winter**
At depth of 00 cm	2.29	1.80	4.11	7.76
At depth of 10 cm	2.60	2.04	4.69	8.82
At depth of 20 cm	2.94	2.31	5.31	9.97
At depth of 30 cm	3.30	2.59	5.97	11.20

*Absorption spectra of typical river water sample (River Rhine at an unspecified location) were used to calculate environmental half-life time in natural water down to a depth of 30 cm. Conditions: sampled river water at depth of 0 – 30 cm, terrestrial type of atmosphere, typical ephemeride and ozone values.

	Evaluation by Competent Authorities
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	11 July 2012
Materials and Methods	The Applicant's version is considered to be acceptable.
Results and discussion	The Applicant's version is considered to be acceptable.
Conclusion	The Applicant's version is considered to be acceptable.
Reliability	Accepted as being 1
Acceptability	The Applicant's version is considered to be acceptable.
Remarks	Based upon results from the study performed to EPA OPPTS 835.2210 guidelines, dinotefuran has been predicted to rapidly photolyse in river water under typical Northern European environmental conditions. Therefore, if dinotefuran emissions should reach surface water in significant concentrations, phototransformation could be a major process for its removal from the aquatic environment provided that surface waters are relatively free from suspended sediment (half-lives of 1.80 – 7.76 d at 40° N depending upon season have been determined based upon studies performed using pure water). Although this has been extrapolated to half-lives in natural water using absorption spectrum from a typical river sample (unspecified point on River Rhine but presumably in Switzerland), it must be assumed that the sample would therefore have low turbidity.
	COMMENTS FROM ...
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

Section A7.1.1.2.1 Ready Biodegradability

Annex Point IIA7.6.1.1

1 REFERENCE

			Official use only
1.1	**Reference**	Feil-Klein, N., 2012, Ready biodegradability of dinotefuran technical in a manometric respirometry test, IBACON GmbH, unpublished report no. 70891163, March 8, 2012	
1.2	**Data protection**	Yes	
1.2.1	Data owner	Mitsui Chemicals Agro, Inc.	
1.2.2	Criteria for data protection	Data on new a.s. for first entry to Annex I	

2 GUIDELINES AND QUALITY ASSURANCE

2.1	**Guideline study**	Yes ☐Commission Regulation 440/2008/EC, Method C.4-D OECD 301 F	
2.2	**GLP**	Yes	
2.3	**Deviations**	No	

3 MATERIALS AND METHODS

3.1	**Test material**	As given in section 2 (namely Dinotefuran technical)	
3.1.1	Lot/Batch number	K09A3559	
3.1.2	Specification	As given in section 2	
3.1.3	Purity	99.4 %	
3.1.4	Further relevant properties	Solubility in water: 39.83 g/L at 20 °C Stability in water:> 24 hours (Sponsor information) ThOD$_{NH4}$: 0.950 mg oxygen per mg test item (calculated by IBACON according to structural formula) ThOD$_{NO3}$: 2.216 mg oxygen per mg test item (calculated by IBACON according to structural formula)	X
3.1.5	Composition of Product	n.a.	
3.1.6	TS inhibitory to microorganisms	No	
3.1.7	Specific chemical analysis	No	
3.2	**Reference substance**	Yes, Sodium benzoate	
3.2.1	Initial concentration of reference substance	102 mg/L (corresponding to ThOD$_{NH4}$ of approximately 170 mg/L)	
3.3	**Testing procedure**		

3.3.1	Inoculum / test species	see Table A7.1.1.2.1-2
3.3.2	Test system	see Table A7.1.1.2.1-3
3.3.3	Test conditions	see Table A7.1.1.2.1-4
3.3.4	Method of preparation of test solution	Analytical grade salts were added to deionised water to prepare the following stock solutions: a) 8.5 g KH_2PO_4, 21.75 g K_2HPO_4, 33.4 g $Na_2HPO_4.2H_2O$, 0.5 g NH_4Cl filled up with deionised water to 1000 mL volume b) 22.5 g $MgSO_4.7H_2O$ filled up with deionised water to 1000 mL volume c) 36.4 g $CaCl_2.2H_2O$ filled up with deionised water to 1000 mL volume d) 0.25 g $FeCl_3.6H_2O$ filled up with deionised water to 1000 mL volume In order to avoid precipitation of iron hydroxide in the stock solution d) after storage and before use, one drop of concentrated HCl per litre was added. 10 mL of stock solution a) and 1 mL of the stock solutions b) to d) were combined and filled up to a final volume of 1000 mL with deionised water. The pH-value was 7.3 and 7.5 and therefore no adjustment was necessary.
3.3.5	Initial TS concentration	104 and 102 mg/L
3.3.6	Duration of test	28 days
3.3.7	Analytical parameter	Oxygen consumption
3.3.8	Sampling	Cumulative biochemical oxygen demand (mg O_2/L) in test flasks was recorded daily.
3.3.9	Intermediates/ degradation products	Not identified
3.3.10	Nitrate/nitrite measurement	No
3.3.11	Controls	Inoculum control (inoculum only) Procedure control (reference item and inoculum) Abiotic control (test item and $HgCl_2$) Toxicity control (test item, reference item and inoculum)
3.3.12	Statistics	The biodegradability (% BOD = mg O_2 per mg test item) exerted after each period was calculated as: $\text{BOD} = \dfrac{\text{mg O}_2\text{ uptake of test item - mg O}_2\text{ uptake of inoculum control}}{\text{mg test item in flask}}$ The percentage biodegradation of the test item and of the reference item sodium benzoate was calculated as: $\text{\% degradation} = \dfrac{\text{BOD (mg O}_2\text{/mg test item or reference item)}}{\text{ThOD}_{\text{NH4}}\text{ (mg O}_2\text{/mg test item or reference item)}} \text{ x } 100$

Section A7.1.1.2.1 Ready Biodegradability

Annex Point IIA7.6.1.1

Or in case of nitrification of the test item:

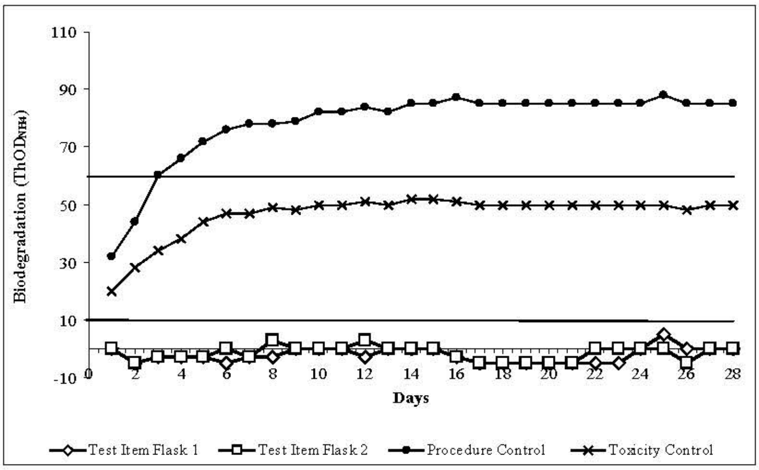
$$\% \text{ degradation} = \frac{\text{BOD (mg } O_2\text{/mg test item or reference item)}}{\text{ThOD}_{NO3} \text{ (mg } O_2\text{/mg test item or reference item)}} \text{ x } 100$$

The ThOD_{NH4} of dinotefuran technical was calculated to be 0.950 mg O_2/mg test item. If nitrification occurs, the ThOD_{NO3} of dinotefuran technical was calculated to be 2.216 mg O_2/mg test item.

4 RESULTS

4.1 Degradation of test substance

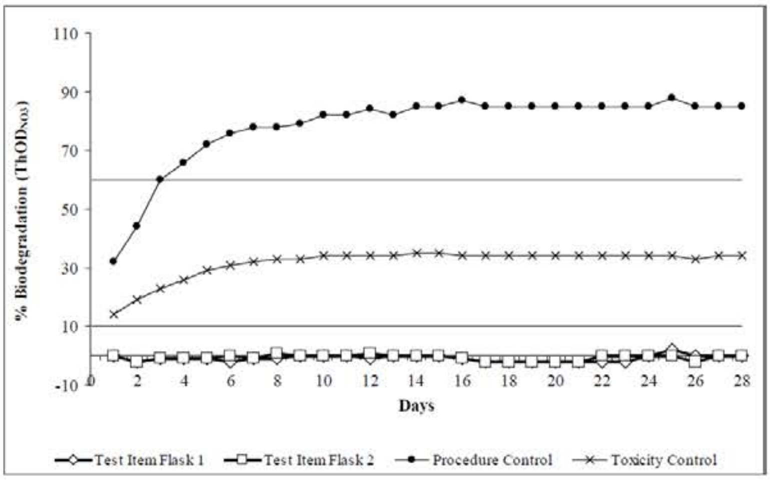
4.1.1 Graph



Biodegradation of dinotefuran technical (flasks 1 and 2), of the reference item sodium benzoate (procedure control) and of the toxicity control during the exposure period of 28 days related to ThOD_{NH4}

Section A7.1.1.2.1 Ready Biodegradability

Annex Point IIA7.6.1.1



Biodegradation of dinotefuran technical (flasks 1 and 2), of the reference item sodium benzoate (procedural control) and of the toxicity control during the exposure period of 28 days related to ThOD$_{NO3}$

4.1.2 Degradation 0 %

4.1.3 Other observations

The reference item sodium benzoate was sufficiently degraded to 85% after 14 days and after 28 days of incubation.

In the toxicity control containing both the test item and reference, 52% (ThOD$_{NH4}$) and 35% (ThOD$_{NO3}$) biodegradation was noted within 14 days and 50% (ThOD$_{NH4}$) and 34% (ThOD$_{NO3}$) biodegradation was determined after 28 days of incubation.

According to the validity criteria of OECD test guideline 301F, the test item can be assumed to be not inhibitory on the aerobic activated sludge microorganisms

4.1.4 Degradation of TS in abiotic control 0 %

4.1.5 Degradation of reference substance see 4.1.1

4.1.6 Intermediates/ degradation products not applicable

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

The test item dinotefuran technical was investigated for its ready biodegradability in a manometric respirometry test over a period of 28 days. The biodegradation was followed by the oxygen uptake of the microorganisms during exposure. As a reference item sodium benzoate was tested simultaneously under the same conditions as the test item, and functioned as a procedure control.

Aerobic activated sludge (micro-organisms from a domestic wastewater treatment plant) supplied by the sewage works at Rossdorf, Germany was used as inoculum.

The endpoint of the study was the degradation rate of the test item calculated by the oxygen consumption of the aerobic activated sludge microorganisms after 28 days of incubation.

The arithmetic mean test item loading rate was 103 mg/L (corresponding to an oxygen demand of about 98 mg/L ($ThOD_{NH4}$) and 228 mg/L ($ThOD_{NO3}$)). The reference item loading rate was 102 mg/L (corresponding to an oxygen demand of about 98 mg/L ($ThOD_{NH4}$) and 228 mg/L ($ThOD_{NO3}$)).

The study was conducted in the dark at 21 – 22 °C.

The study was performed according to the following guidelines:

- Commission Regulation 440/2008/EC, Method C.4-D
- OECD Guideline for Testing of Chemicals No. 301 F

5.2 Results and discussion

The test item dinotefuran technical contains nitrogen, therefore the evaluation of biodegradation has to be based on $ThOD_{NH4}$ and $ThOD_{NO3}$. The criterion for ready biodegradability under the conditions of a manometric respirometry test is the 10-day window, describing the period between reaching at least 10% degradation and 60% degradation. This period should not exceed 10 days.

The mean biodegradation after 28 days of dinotefuran technical was 0% ($ThOD_{NH4}$) and ($ThOD_{NO3}$); the 10 day window criterion was not passed.

Therefore, dinotefuran technical is considered not to be readily biodegradable.

The reference item sodium benzoate was sufficiently degraded to 85% after 14 days and after 28 days of incubation, thus confirming the suitability of the aerobic activated sludge inoculum used.

In the toxicity control containing both, the test item and the reference item sodium benzoate, 52% ($ThOD_{NH4}$) and 35% ($ThOD_{NO3}$) biodegradation was noted within 14 days and 50% ($ThOD_{NH4}$) and 34% ($ThOD_{NO3}$) biodegradation after 28 days of incubation. Thus, the test item can be assumed to be not inhibitory to the aerobic activated sludge micro organisms.

5.3 Conclusion

The degradation rate of dinotefuran technical did not reach 60% within the 10-day window and after 28 days of incubation.

Therefore, dinotefuran technical is considered not to be readily biodegradable.

The percentage biodegradation of the reference item confirms the suitability of the used aerobic activated sludge inoculum.

According to the validity criteria of OECD test guideline 301F, the test item can be assumed to be not inhibitory on the aerobic activated sludge microorganisms because degradation was >25% within 14 days.

5.3.1 Reliability 1

5.3.2 Deficiencies No

Table A7.1.1.2.1-1: Guideline-methods of EC and OECD for tests on ready/inherent biodegradability (according to OECD criteria); simulation test

Test	EC-method	OECD-Guideline	Test on ready/inherent biodegradability
DOC Die-Away-Test	C.4-A	301A	ready
CO_2 Evolution-Test (Modified Sturm Test)	C.4-C	301B	ready
Modified OECD-Screening-Test	C.4-B	301E	ready
Manometric Respirometry	C.4-D	301F	ready
MITI-I-Test	C.4-F	301C	ready
Closed-Bottle-Test	C.4-E	301D	ready
Zahn-Wellens-test	C.9	302B	Inherent
Modified MITI-Test (II)	-	302C	Inherent
Modified SCAS-Test	C.12	302A	Inherent
Simulation Test with activated Sewage (Coupled Units-Test)	C.10	302A	Simulation Test 1)

1) Test for the determination of the ultimate degradation of test material under conditions which simulate the treatment in an activated sludge plant

Table A7.1.1.2.1-2: Inoculum / Test organism

Criteria	**Details**
Nature	activated sludge (aerobic)
Species	n.a.
Strain	n.a.
Source	Sewage treatment plant treating predominantly domestic sewage
Sampling site	Sewage plant at Rossdorf, Germany.
Laboratory culture	No
Method of cultivation	n.a.
Preparation of inoculum for exposure	The sediment was resuspended in test water and aerated overnight following 3 x washing/centrifugation/re-suspension in tap water
Pretreatment	No
Initial cell concentration	1.5 g/L dry material

Table A7.1.1.2.1-3: Test system

Criteria	**Details**
Culturing apparatus	e.g. respirometer
Number of culture flasks/concentration	2
Aeration device	n.a.
Measuring equipment	BSB/BOD-Sensor-System, Aqualytic Dortmund, Germany
Test performed in closed vessels due to significant volatility of TS	n.a.

Table A7.1.1.2.1-4: Test conditions

Criteria	**Details**
Composition of medium	Analytical grade salts were added to deionised water to prepare the following stock solutions: a) 8.5 g KH_2PO_4, 21.75 g K_2HPO_4, 33.4 g $Na_2HPO_4.2H_2O$, 0.5 g NH_4Cl filled up with deionised water to 1000 mL volume b) 22.5 g $MgSO_4.7H_2O$ filled up with deionised water to 1000 mL volume c) 36.4 g $CaCl_2.2H_2O$ filled up with deionised water to 1000 mL volume d) 0.25 g $FeCl_3.6H_2O$ filled up with deionised water to 1000 mL volume In order to avoid precipitation of iron hydroxide in the stock solution d) after storage and before use, one drop of concentrated HCl per litre was added. 10 mL of stock solution a) and 1 mL of the stock solutions b) to d) were combined and filled up to a final volume of 1000 mL with deionised water. The pH-value was 7.3 and 7.5 and therefore no adjustment was necessary.
Additional substrate	No
Test temperature	21 – 22 ° C
pH	7.6 (measured at the start of the test) 6.8–7.6 (measured at the end of the test)
Aeration of dilution water	No
Suspended solids concentration	ca. 30mg/L
Other relevant criteria	continuous stirring

Table A7.1.1.2_1-5: Pass levels and validity criteria for tests on ready biodegradability

	Fulfilled	Not fulfilled
Pass levels		
70% removal of DOC resp. 60% removal of ThOD or $ThCO_2$		X
Pass values reached within 10-d window (within 28-d test period) - not applicable to MITI-I-Test - 14-d window acceptable for Closed-Bottle-Test		X
Criteria for validity		
The oxygen uptake of the inoculum blank is normally 20-30 mg O_2/L and should not be greater than 60 mg O_2/L in 28 days. Values higher than 60 mg/L require critical examination of the data and experimental technique. If the pH value is outside the range 6.0-8.5 and the oxygen consumption by the test substance is less than 60%, the test should be repeated with a lower concentration of test substance.	X	
A test is considered valid if the difference of extremes of replicate values of the removal of the test chemical at the plateau, at the end of the test or at the end of the 10-d window, as appropriate, is less than 20% and if the percentage degradation of the reference compound has reached the pass levels by day 14.	Not applicable *	
The percentage degradation of the reference item should reach the level for ready biodegradability (>60%) within 14 days as required by the test guideline.	X	

* Since the biodegradation did not reach the pass criterion of 60% degradation and no 10 day-window could be determined, the validity criterion was not applicable. At the end of the experiment, no difference in replicate variation was determined.

Evaluation by Competent Authorities

EVALUATION BY RAPPORTEUR MEMBER STATE

Date	9 July 2012
Materials and Methods	The Applicant's version is considered to be acceptable, noting the following :– **3.1.4** : Information of water solubility has been taken from the Applicant's data set and reported in Doc III-A3.5 (for pH 6.98).
Results and discussion	The Applicant's version is considered to be acceptable.
Conclusion	The Applicant's version is considered to be acceptable.
Reliability	Accepted as being 1
Acceptability	The Applicant's version is considered to be acceptable.
Remarks	It is quite clear that, based upon test results from this study performed to OECD 301F methodology, dinotefuran must be classified as not readily biodegradable.

COMMENTS FROM ...

Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

Section 7.1.1.2.2 **Annex Point IIIA, XII.2.1**	**Biodegradability (inherent)**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	**Official use only**
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [X]**	
Detailed justification:	A test for the inherent biodegradability of dinotefuran has not been performed. In a ready biodegradability test (Section A7.1.1.2.1) dinotefuran is found to not be readily biodegradable. The non-ready biodegradability of dinotefuran has been incorporated into the relevant environmental risk assessments. Thus this test is not required.	
Undertaking of intended data submission [ ]	Not applicable	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	11 July 2012	
Evaluation of applicant's justification	The Applicant has submitted a ready biodegradation study (performed to OECD 301F methodology) which demonstrates 0% degradation over the 28 d test period. It must therefore be assumed that performance of an inherent biodegradation study is considered to add little or no further value to the dinotefuran package. Refinement of emissions will only be driven by potential degradation identified in studies looking at specific environmental compartments.	
Conclusion	The Applicant's justification is considered to be acceptable.	
Remarks	None	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date		
Evaluation of applicant's justification		
Conclusion		
Remarks		

Section 7.1.1.2.3 **Annex Point IIIA, XII.2.1**	**Biodegradation in seawater**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	**Official use only**
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [X]**	
Detailed justification:	Dinotefuran is not intended for use or release to marine environments, therefore a seawater biodegradation test is not required.	
Undertaking of intended data submission [ ]	Not applicable	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	11 July 2012	
Evaluation of applicant's justification	The representative product will be applied in small quantities indoors in relatively inaccessible areas so emissions to surface waters will be limited to any material picked up during cleaning processes. There are no direct emissions of product containing dinotefuran to the marine environment and indirect exposure is considered extremely unlikely. As a consequence, the submission of such a study would appear unnecessary.	
Conclusion	The Applicant's justification is considered to be acceptable.	
Remarks	None	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date		
Evaluation of applicant's justification		
Conclusion		
Remarks		

Section 7.1.2.1.1 **Annex Point IIIA, XI.2.1**	**Aerobic biodegradation**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	**Official use only**
Other existing data [X] **Limited exposure [X]**	**Technically not feasible [ ]** **Scientifically unjustified [X]** **Other justification [ ]**	
Detailed justification:	Dinotefuran 2% bait is intended for only professional use indoors by application in locations normally inaccessible after application to man and domestic animals and not on surfaces that are wet cleaned. These labelling requirements limit the exposure of dinotefuran and only negligible amounts will enter a sewage treatment plant (STP). No test has been performed about the elimination of dinotefuran in STP. For the environmental risk assessment, it is therefore assumed that 100% of the product that enters the STP also leaves the STP in the effluent. Please refer to Dossier Document II-B for the environmental risk assessment according to TGD on Risk Assessment.	
Undertaking of intended data submission [X]	Product specific data will be addressed during product application when necessary.	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	16 January 2013	
Evaluation of applicant's justification	Due to the restricted indoor use pattern of the representative product (cockroach gel bait), the ESD for PT 18 predicts limited emissions to local STP based on a maximum cleaning efficiency of 3%. An STP simulation study has not been performed on that basis so no refinement of emissions to receiving watercourses can be made accounting for (bio)degradation within the treatment works. Therefore EUSES 2.1.2 modelling predicts >99.9% of dinotefuran passing through the STP unchanged to the receiving water body.	
Conclusion	The Applicant's justification is considered to be acceptable.	
Remarks	None	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date		
Evaluation of applicant's justification		
Conclusion		
Remarks		

Section 7.1.2.1.2 **Annex Point IIIA, XII.2.1**	**Anaerobic biodegradation**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	**Official use only**
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [X]** **Other justification [ ]**	
Detailed justification:	An anaerobic degradation study is required if exposure to anaerobic conditions is likely. This may be the case with veterinary hygiene biocidal products and biocidal pest control products to be used in animal housing where release into manure storage facilities is possible. It is not likely that dinotefuran will be exposed to anaerobic conditions and is not intended for use in animal housing, therefore an anaerobic biodegradation test is not required.	
Undertaking of intended data submission [ ]	Not applicable	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	16 January 2013	
Evaluation of applicant's justification	Due to the restricted indoor use pattern of the representative product (cockroach gel bait applied by professional operators) with limited emissions only to drains following wet cleaning, it is clear that exposure of dinotefuran to anaerobic conditions is extremely unlikely.	
Conclusion	The Applicant's justification is considered to be acceptable.	
Remarks	None	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date		
Evaluation of applicant's justification		
Conclusion		
Remarks		

Section 7.1.2.2.1 **Annex Point IIIA, XI.2.1**	**Aerobic aquatic degradation study**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	**Official use only**
Other existing data [ ] **Limited exposure [X]**	**Technically not feasible [ ]** **Scientifically unjustified [X]** **Other justification [ ]**	
Detailed justification:	This test is required if the biocide is directly emitted to water. Dinotefuran is intended for indoor use therefore this test is not required. See Section A7.1.2.2.2 for water/sediment degradation test results and Section A7.1.3 for adsorption/desorption test results.	
Undertaking of intended data submission [ ]	Not applicable	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	16 January 2013	
Evaluation of applicant's justification	Due to the restricted indoor use pattern of the representative product (cockroach gel bait), the ESD for PT 18 predicts limited emissions to local STP based on a maximum cleaning efficiency of 3%. Therefore, no direct emission to surface waters can be predicted. In addition, the Applicant has submitted a water-sediment degradation study (under **A7.1.2.2.2**) for both a pond and river system as a means of predicting potential degradation within receiving waterbodies.	
Conclusion	The Applicant's justification is considered to be acceptable.	
Remarks	None	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date		
Evaluation of applicant's justification		
Conclusion		
Remarks		

Section A7.1.2.2.2 Water/sediment degradation study

Annex Point IIIA XII.2.1

			Official use only
		1 REFERENCE	
1.1	**Reference**	Völkel W., 2000, ^{14}C-MTI-446 : Degradation and Metabolism in Aquatic Systems. RCC Ltd, Itingen, Switzerland; unpublished report no. 709604, October 20, 2000.	
1.2	**Data protection**	Yes	
1.2.1	Data owner	Mitsui Chemicals Agro, Inc.	
1.2.2	Criteria for data protection	Data on new a.s. for first entry to Annex I	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes Commission Directive 95/36/EC of 14 July 1995 amending Council Directive 91/414/EEC: Annex I: 7.2.1.3.2 Water/Sediment Study. SETAC Europe: Guideline 8.2 EPA 540/9-82-021, Section 162-4	
2.2	**GLP**	Yes	
2.3	**Deviations**	No	
		3 MATERIALS AND METHODS	
3.1	**Test material**	Dinotefuran (non-labelled and ^{14}C labelled) supplied as MTI-446	
3.1.1	Lot/Batch number	Non-labelled test item: EBI-5-101 Labelled test item: Batch No. VB9303(G-label) and VB9301(F-label) mixed in equal amounts	
3.1.2	Specification	As given in section 2 (namely Doc III-A2)	
3.1.3	Purity	Non-labelled test item: 99.6% Labelled test item: 98.6% (radiochemical purity)	X
3.1.4	Radiolabelling	G-label (guanidine side chain label), F-label (furanyl ring label)	
3.1.5	Further relevant properties	Melting point: 107.5 °C Density at 20 °C: 1.40 g/cm^3 Vapour pressure at 30 °C: < 1.7x10^{-6} Pa Solubility in water at 20 °C: 39.83 g/L	X
3.1.6	TS inhibitory to microorganisms	No	
3.1.7	Analytical methods	HPLC was used to quantify the ^{14}C-dinotefuran in the water/sediment samples, whilst TLC analysis was used to confirm the results obtained by HPLC. LSC was used for radioactivity quantification.	
3.2	**Transformation products**	Yes Main transformation product characterised as DN : 1-methyl-3-(tetrahydro-3-furylmethyl)guanidine	
3.2.1	Method of analysis for transformation	Characterisation by HPLC and TLC co-chromatography with reference standard	

	products		
3.3	**Reference substance**	No	
3.4	**Testing procedure**		
3.4.1	Test Sediment/water	See Table A7.1.2.2.2-1	
3.4.2	Test system	See Table A7.1.2.2.2-2	
3.4.3	Test conditions	See Table A7.1.2.2.2-3	
3.4.4	Method of preparation of test solution	Initial concentrate solutions of both radiolabelled compounds were prepared in acetone. Aliquots of both concentrates were taken, the solvent evaporated and re-dissolved in purified water. The final dosing solution was prepared with aliquots of the stock solutions prepared with the F-label and G-label.	
3.4.5	Initial TS concentration	0.050 mg/l	X
3.4.6	Duration of test	320 days after application	
3.4.7	Analytical extraction procedure and sample preparation	After sampling, the water phase was separated from the sediments by pipette. The radioactivity in the water was measured by LSC, the volume reduced under reduced pressure at 30 - 40°C and submitted to HPLC analysis. The sediments were extracted 1-2 times with acetonitrile:water (8:2 v/v), once with water and a further extraction with Soxhlet and acetonitrile:water (8:2 v/v) in all samples except days 0, 1 and 2. After LSC quantification, samples were combined and concentrated under reduced pressure at 30-40°C before HPLC analysis. After extraction, the sediments were dried, weighed, homogenised and combusted for determination of their radioactivity by LSC. Aliquots of the extracted sediments were subject to organic matter fractionation by extraction with NaOH and precipitation with HCl. Volatile radioactivity was trapped during the study with NaOH traps (CO_2) and ethylene glycol (organic volatiles). These solutions were then analysed by LSC.	
3.4.8	Sampling	Immediately after application (day 0) and after 1, 2, 7, 14, 28, 56, 103, 141, 180, 258 and 320 days of incubation, one sample of each system was taken for analysis.	
3.4.9	Intermediates/ degradation products	Chromatographic analysis for characterisation of degradation products and quantification of the parent compound was as follows: HPLC method: Pre-column, LiChrospher 100 C18 (4 mm × 4 mm, 5μm) Column, Ultrasphere ODS (250 mm × 4.6 mm, 5μm), gradient method with 10 mM octanesulfonic acid (solvent A) and methanol (Solvent B), at room temperature and a 1 mL/minute flow rate. UV detection at 220 nm and ^{14}C detection with a liquid scintillant cell. TLC method: Silica gel 60 F_{254} plates and RP-18 plates, 0.25 mm without chamber	

Section A7.1.2.2.2 Water/sediment degradation study

Annex Point IIIA XII.2.1

saturation. A variety of 11 solvent systems was used. UV detection at 254 nm plus radiolabelled detection with TLC linear analyser.

3.4.10 Controls

No controls were used other than for the physico-chemical parameters of pH, Oxygen, redox, organic carbon, and microbial biomass.

3.4.11 Statistics

DT_{50} and DT_{90} degradation kinetics were calculated with the MicroCal Origin v3.5 program. First order kinetics were performed using the Levenberg-Marquardt minimisation.

4 RESULTS

4.1 Degradation of test substance

4.1.1 Graph

See Figures A7.1.2.2.2-1 to A7.1.2.2.2-4 for degradation graphs. X

4.1.2 Degradation

In the experiment, total recoveries of radioactivity (mass balances) were generally 95.2±5.9% applied radioactivity (AR) for the river system and 96.6±3.7% for the pond system. In the last sampling point at 320 days after application, the recoveries went below 90% in the river system. Total radioactivity in water declined from 98% on day 0 to 8.3% AR on day 320 in the river, and from 98.4% to 2.6% AR in the pond. There were corresponding increases with time in sediment radioactivity with maxima of 50.4% AR in the river (day 141) and 77.3% in the pond system (day 180). Of the radioactivity associated with the sediment, non-extractable residues also increased with time to maxima of 29.5% AR in the river and 62.9% AR in the pond system. Volatile radioactivity, all associated with $^{14}CO_2$, represented a maximum of 34.9% AR in the river samples and 19.9% AR in the pond samples.

DT_{50} values were calculated as follows:

	Aerobic DT_{50} [days] at 20 °C	
	River	Pond
Water	49.2	23.0
Sediment	45.0	128.0
Total system	56.7	44.5

X

A summary of the results is given in tabular form in Table A7.1.2.2.2-4 to Table A7.1.2.2.2-5

4.1.3 Other observations – physico-chemical determinations

Physico-chemical parameters stayed relatively constant throughout the study and were in the expected range for this type of study. No effects of the test substance were observed on the microbial activity of the water/sediment systems.

Non extractable material was found mainly in the immobile humic acid and humin fractions. Radioactivity associated with the fulvic acids was approximately 12% of the applied dose.

4.1.4 Degradation of TS in abiotic control

No abiotic control used.

4.1.5 Degradation of reference substance

No reference substance used

Section A7.1.2.2.2 Water/sediment degradation study

Annex Point IIIA XII.2.1

4.1.6 Intermediates/ degradation products

Dinotefuran mainly degraded to DN, reaching a maximum amount of 23.1% and 32.6% AR in the river and pond system at 180 and 103 days, respectively. Additionally up to 5 minor degradation products were formed but never exceeding 3.9% of AR. Half lives for the degradation product DN could be calculated as :

	Aerobic DT_{50} [days] at 20 °C	
	River	Pond
Total system	114.0	80.0

X

A summary of the results is given in tabular form in Table A7.1.2.2.2-4 to Table A7.1.2.2.2-5

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

Guidelines:

Degradation in water/sediment systems was studied according to the SETAC Europe: Guideline 8.2 and EPA 540/9-82-021, Section 162-4 guideline. No relevant deviations from test guidelines.

5.2 Results and discussion

The degradation of dinotefuran under aerobic conditions was studied with ^{14}C labelled test substance in two different labels. Two water/sediment systems of differing properties were selected.

In the experiment, total recoveries of radioactivity (mass balances) were generally 95.2±5.9% of applied radioactivity (AR) for the river system and 96.6±3.7% for the pond system. In the last sampling point at 320 days after application, the recoveries went below 90% in the river system. Total radioactivity in water declined from 98% on day 0 to 8.3% AR on day 320 in the river, and from 98.4% to 2.6% AR in the pond. There were corresponding increases with time in sediment radioactivity with maxima of 50.3% AR in the river (day 141) and 77.2% in the pond system (day 180). Of the radioactivity associated with the sediment, non-extractable residues also increased with time to maxima of 29.5% AR in the river and 62.4% AR in the pond system. Volatile radioactivity, all associated with $^{14}CO_2$, represented a maximum of 34.4% AR in the river samples and 19.9% AR in the pond samples (day 258 for both water sources). Degradation half lives in the total system of 56.7 and 44.5 days were calculated (river and pond respectively).

Chromatographic profiles were qualitatively similar between aquatic sediments. A significant metabolite in both the aerobic and anaerobic experiments was DN, formed by loss of the 2-nitro group. This degradation product accounted for up to 32.6% AR in the total system. A number of minor degradation products were formed, none individually accounting for more than 3.3% AR in any system.

5.3 Conclusion

Dinotefuran declined from the water of aerobic aquatic sediment systems with calculated DT_{50} values of 49.2 and 23.0 days (river and pond system respectively). Corresponding DT_{50} values for sediments were 45.0 and 128.0 days plus, for the total system, 56.7 and 44.5 days respectively.

X

One major degradation product was formed, DN, which accounted for up to 32.6% of the AR (day 103 in both systems). DT_{50} values of 114 and 80 days were calculated for DN in the river and pond system respectively.

5.3.1 Reliability 1

5.3.2 Deficiencies No

Table A7.1.2.2.2-1: Soil types and their characteristics

Parameters	System 1	System 2
Site location	River (Rhine)	Pond
Origin	Mumpf, Switzerland	Judenweiher, Switzerland
Date of sampling	15 October 1998	15 October 1998
Water		
Temperature at sampling [°C]	13.7	12.7
pH	8.06	7.74
Oxygen [mg/L]	9.5	9.5
Redox [mV]	217	215
Organic carbon [mg/L]	13.7	25.6
Total nitrogen [mg/L]	9.5	4.5
Total phosphorus [mg/L]	0.12	0.07
Hardness [°dH]	10	18
Sediment		
Particle size analysis (USDA):	[SANDY LOAM]	[LOAM]
< 0.002 (clay) %	7.6	17.7
0.002 – 0.05 (silt) %	15.2	35.2
> 0.05 (sand) %	77.2	47.1
pH [0.01M $CaCl_2$]	7.43	6.47
Redox [mV]	-131	-123
Organic carbon [g/100 g sediment] %	0.67	3.1
Cation exchange capacity [mmol/kg soil]	63.1	196.7
Dry mass [kg wet/kg dry]	1.5	2.2
Nitrogen content [g/kg]	0.060	0.417
Phosphorus content [g/kg]	0.188	0.228

Table A7.1.2.2.2-2: Test system

Criteria	Details		
Vessel type	1000 ml glass metabolism flasks		
Vessel replicates			
Number of vessels	Test	Treatment rate [mg/L]	Radiolabel
12 per sediment	Aerobic, main	0.05	Mixture of F and G
8 per sediment	Physico-chemical parameters	-	-

Table A7.1.2.2.2-3: Test conditions

Parameters	River		Pond	
Test temperature [°C]	20 ± 1			
Light conditions	dark			
Water/sediment ratio	About 3:1			
Aeration	Humidified air			
	Start	End	Start	End
pH in water throughout exposure	8.06	8.0	7.74	7.88
pH in sediment throughout exposure	7.43	-	6.47	-
Oxygen saturation of water [mg/l]	9.5	6.8	9.5	6.4
Redox in water throughout exposure [E_h, mV]	217	189	215	180
Redox in sediment throughout exposure [E_h, mV]	-131	-57.5	-123	-92.5
Microbial biomass [g microbial C/kg dry sediment]	0.32	0.42	1.14	1.17

Table A7.1.2.2.2-4: Distribution and recovery of radioactivity in aerobic river system [as % of AR]

Sample	Time after application [days]											
	0	1	2	7	14	28	56	103	141	180	258	320
Water	98.0	93.5	87.5	82.5	77.5	64.6	48.8	30.7	21.6	18.1	16.0	8.3
Extractable sediment	n.d.	7.4	10.4	16.0	18.1	26.3	24.7	20.4	20.9	20.7	12.0	9.2
Non-extractable sediment	0.1	0.4	0.8	1.4	3.4	5.7	17.3	24.3	29.5	29.0	28.8	28.2
Organic volatiles	-	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1
CO_2	-	n.d.	n.d.	0.2	0.5	1.6	4.5	14.8	20.8	28.2	34.4	34.9
Total recovery	98.1	101.3	98.7	100.1	99.6	98.3	95.3	90.1	92.7	95.9	91.2	80.6
Identified as parent	98.0	100.9	97.9	97.2	88.5	74.4	50.4	26.5	17.0	14.0	12.2	7.0
Identified as DN	n.d.	n.d.	n.d.	n.d.	5.6	13.3	20.6	20.7	22.2	23.1	14.8	9.0

n.d. : not detected or below limit of quantification

DN : l-methyl-3-(tetrahydro-3-furylmethyl) guanidine

Minor degradation products are not listed in the table (individual values all represent <2.5% of AR)

Table A7.1.2.2.2-5: Distribution and recovery of radioactivity in aerobic pond system [as % of AR]

Sample	Time after application [days]											
	0	1	2	7	14	28	56	103	141	180	258	320
Water	98.4	89.1	82.7	75.9	59.3	41.5	23.4	11.8	7.7	5.4	3.0	2.6
Extractable sediment	3.5	9.6	14.8	21.0	33.4	29.0	36.7	46.4	29.7	22.6	12.4	13.2
Non-extractable sediment	0.3	0.7	1.6	2.8	5.9	21.8	31.3	25.4	43.6	54.7	62.4	62.9
Organic volatiles	-	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1
CO_2	-	<0.1	<0.1	0.1	0.7	1.2	2.3	7.3	10.3	14.8	19.9	15.7
Total recovery	102.2	99.4	99.1	99.8	99.3	93.5	93.7	90.9	91.3	97.5	97.7	94.4
Identified as parent	101.9	98.7	97.5	95.2	81.9	58.4	37.0	24.0	18.1	11.3	7.3	7.6
Identified as DN	n.d.	n.d.	n.d.	n.d	8.6	8.8	20.1	32.6	18.8	15.2	8.1	7.8

n.d. : not detected or below limit of quantification

DN : l-methyl-3-(tetrahydro-3-furylmethyl) guanidine

Minor degradation products are not listed in the table (individual values all represent <3.5% of AR)

Figure A7.1.2.2.2-1: Degradation graph of dinotefuran – total river

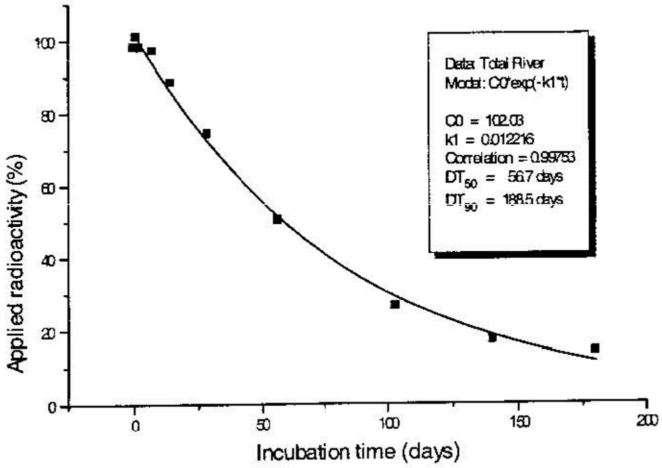


Figure A7.1.2.2.2-2: Degradation graph of dinotefuran – total pond

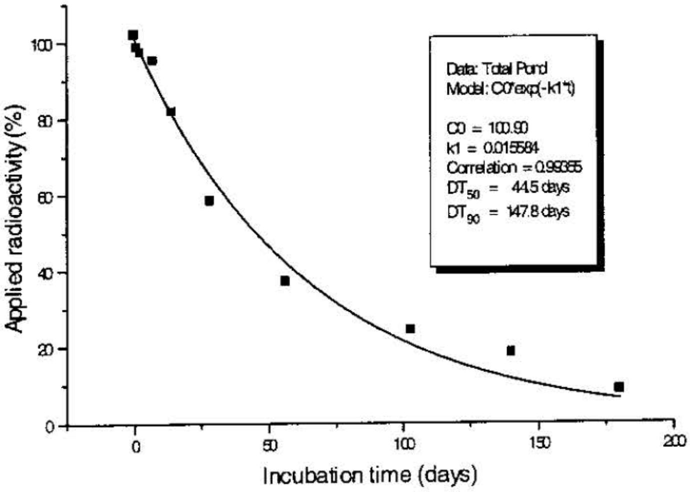


Figure A7.1.2.2.2-3: Degradation graph of DN – degradation in the river

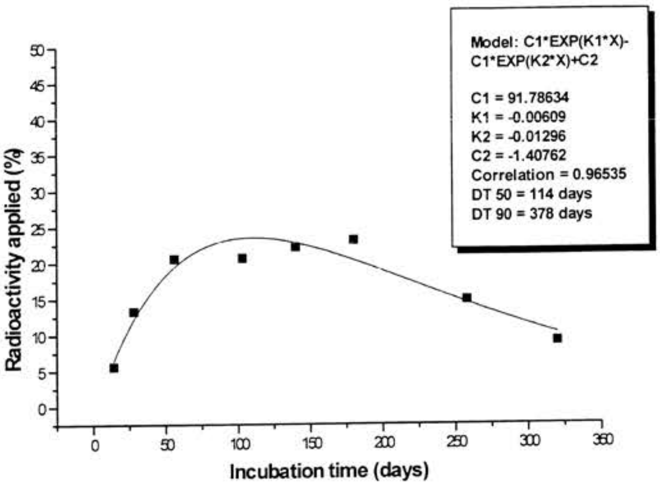
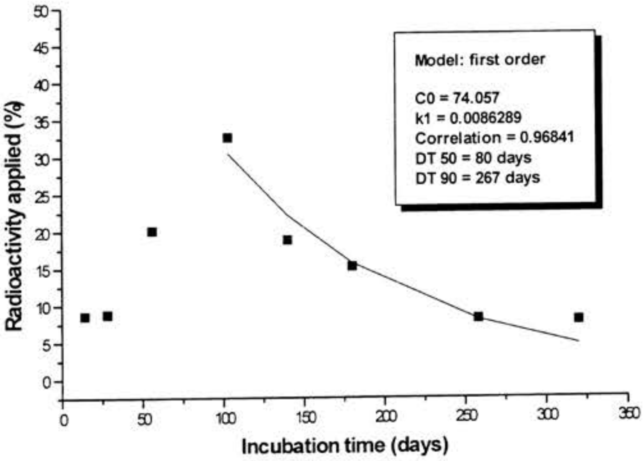


Figure A7.1.2.2.2-4: Degradation graph of DN – degradation in the pond



Evaluation by Competent Authorities

EVALUATION BY RAPPORTEUR MEMBER STATE

Date 13 July 2012

Materials and Methods The Applicant's version is considered to be acceptable, noting the following :-

3.1.3 : It should be noted that the purity value (98.6 %) quoted for radiolabelled dinotefuran is an arithmetic mean value and is based on >99.3% pure (G-label) plus >98.0 % pure (F-label).

3.1.5 : The physico-chemical properties cited in the report differ from those which are detailed in the RSS (melting point of 103.4 – 10.3.7 °C, density not stated, vapour pressure of 5 x 10^{-5} Pa at 25 °C and water solubility of 5.43 g/kg at 20 °C). It is presumed that values given in the RSS actually relate to test values for the compound provided in Doc III-A.3 and supported by study reports.

3.4.5 : The reported initial TS concentration of 50 µg/l is stated to be equivalent to an application rate of 150 g a.s./ha.

Results and discussion The Applicant's version is considered to be acceptable, noting the following :-

4.1.1 The UK CA does not consider the modelling of DN degradation in river system (**Figure A7.1.2.2.2.-3**) to be appropriate as first kinetic modelling has not been used – an equation has been designed simply to fit to metabolite study data (such that C1 and K1 values do not match those determined for the parent in **Figure A7.1.2.2.2-1**). Ideally, kinetic modelling should sequentially model both parent and metabolite together.

4.1.1 Although the approach taken (see **Figure A7.1.2.2.2-4**) to derive the DT_{50} for DN in pond system is an acceptable, conservative approach (in that simple FO kinetics decline modelling has been fitted to study data from peak onwards), the UK CA would consider that sequential modelling of both parent and metabolite would be more appropriate.

4.1.1, 4.1.2, 4.1.6 & 5.3 : As a consequence of concerns over derivation of DT_{50} values for parent and metabolite in both systems, the UK CA has performed confirmatory SFO kinetic modelling (without correction) on the results for degradation of dinotefuran in total river system plus total pond system and has derived similar values to those proposed by the Applicant. When parent and metabolite are modelled together using SFO kinetics, DT_{50} values are observed to change slightly to :-

Compound	DT_{50} (d)	k1 (d^{-1})	r^2	Fraction of parent transformed (%)
Dinotefuran – total river	59.00	0.01175	0.992	47.5
DN – total river system	104.90	0.00661	0.963	
Dinotefuran – total pond	46.55	0.01489	0.985	47.4
DN – total pond system	86.80	0.00799	0.853	

Therefore, in terms of risk assessment, it is proposed to use these revised UK CA DT_{50} values derived at 20 °C and corrected to average EU outdoor temperature.

4.1.2 & 5.3 : The generation of degradation DT_{50} values for each phase (sediment and water) is of limited value in risk determination as the values derived for the water phase represent both degradation plus dissipation into the sediment phase.

Conclusion	The Applicant's version is considered to be acceptable, noting the following :- **5.3** As the UK CA has some concerns over choice of kinetic modelling to determine DT$_{50}$ values, it is proposed that half-lifes from SFO combined modelling of parent & metabolite (see table under RMS comments for **4.11, 4.12, 4.16 & 5.3**) be used for risk assessment purposes.
Reliability	Accepted as being 1
Acceptability	The Applicant's version is considered to be acceptable.
Remarks	Despite a clear lack of degradation reported in a ready biodegradation study (reported under **A7.1.1.2.1**), dinotefuran demonstrates significant degradation in both river and pond systems with predicted total system DT$_{50}$ values at 20 °C of 59.0 d (river) and 46.55 d (pond) assuming first order kinetics. Furthermore, although several metabolites were identified during the study, only one compound (DN) was considered to be major but it too undergoes aerobic degradation in aquatic systems but at a reduced rate compared to that observed for its parent (predicted DT$_{50}$ of 104.9 d in river system and 86.8 d in pond system for DN). It should be noted that significant evolution of radiolabelled $^{14}CO_2$ was detected during the study, reaching a maximum of 34.9 % on day 320 (river) and 19.9 % on day 258 (pond). This indicates quite strongly that dinotefuran will be subject to significant levels of mineralisation in the aquatic environment. Additionally, high levels of non-extractable (i.e. bound) residues were detected in sediment (accounting for 29.5 % AR in river sediment and 62.9 % AR in pond sediment).
	COMMENTS FROM ...
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

Section A7.1.3 Adsorption / Desorption screening test

Annex Point IIA7.7

			Official use only
		1 REFERENCE	
1.1	**Reference**	Völkel, W., 2001, Adsorption/desorption of ^{14}C-MTI-446 on soils; RCC Ltd.; unpublished report no. 728998; September 19, 2001.	
1.2	**Data protection**	Yes	
1.2.1	Data owner	Mitsui Chemicals Agro, Inc.	
1.2.2	Criteria for data protection	Data on new a.s. for first entry to Annex I	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes OECD Guideline 106 (January 21, 2000), Annex, Revision 3 (draft) by the Food Agriculture Organization of United Nations (August 28, 1993), Commission Directive 95/36/EC (July 14, 1995), EPA OPP Guideline N-163-1	
2.2	**GLP**	Yes	
2.3	**Deviations**	No	
		3 MATERIALS AND METHODS	
3.1	**Test material**	As given in section 2	X
3.1.1	Lot/Batch number	Non-labelled test item: EBI-5-101 Labelled test item: CFQ8777 (G-label)	
3.1.2	Specification		
3.1.2.1	Purity	Non-labelled test item: 99.6% Labelled test item: 100% (radiochemical purity)	
3.1.2.2	Stability	Non-labelled test item: Expiry date: December 2003 Labelled test item: Expiry date: not needed since the purity was determined immediately before use.	
3.1.2.3	Further relevant properties	Non-labelled test item: - Melting point: 107.5 °C - Density at 20 °C: 1.40 g/cm^3 - Vapour pressure at 30 °C: $< 1.7 \times 10^{-6}$ Pa - Solubility in water at 20 °C: 39.83 g/L Labelled test item: - Specific radioactivity: 5.0 MBq/mg (G-label)	
3.1.3	Method of analysis	HPLC was used to quantify the ^{14}C-dinotefuran in the water/soil samples, while TLC analysis was used to confirm the results obtained by HPLC. LSC was used for radioactivity quantification.	
3.2	**Degradation products**	Degradation products tested: No	
3.2.1	Method of analysis for degradation products	Not applicable	

Section A7.1.3 Adsorption / Desorption screening test

Annex Point IIA7.7

3.3	**Reference substance**	Yes: dinotefuran non-labelled test item
3.3.1	Method of analysis for reference substance	Not reported
3.4	**Soil types**	See Table A7.1.3-1
3.5	**Testing procedure**	
3.5.1	Test system	Preliminary test: Adsorption behaviour of dinotefuran was studied using two soil types (loamy sand and silt loam) which were tested in this part of the study. Soil samples of 20 g, 4 g, and 1 g respectively, were shaken each with 20 mL of 0.01 M CaCl$_2$ solution, at the test concentration of 0.259 mg ^{14}C-dinotefuran/L. Soil/aqueous phase suspensions were incubated in sealed Teflon® centrifuge tubes on a shaker. Tubes were shaken at about 200 strokes per minute in the dark at 20 °C. Screening test: the adsorption was studied in six different soil types (loamy sand, silt loam, loam, sandy loam, clay loam and sand) by means of adsorption kinetics at a single concentration to determine the distribution coefficients k$_d$ and K$_{oc}$. The soil/solution ratio of 1/1, the weight of the soil sample (10 g), and the volume of the aqueous phase of 10 mL were chosen. Duplicate samples were set-up for each interval. Advanced test: For adsorption isotherms and desorption kinetics/desorption isotherms, with respect to the results obtained in the preliminary and screening tests, the study of the adsorptive behavior of ^{14}C-dinotefuran on soil and its potential mobility was continued by determining Freundlich adsorption isotherms. The procedure for the adsorption isotherms test was similar to that used in the preliminary and screening tests. The desorption experiment was carried out on each sample used in the test for the determination of the adsorption isotherms. After the adsorption, the mixture was centrifuged and the aqueous phase was removed. The volume of supernatant was replaced by an equal volume of 0.01 M CaCl$_2$ without test item. The new mixture was agitated and aliquots of 100 µL were taken from the same sample and analyzed after 4 and 24 hours. Volume of these aliquots did not exceed 4 % of the total aqueous solution volume in order to avoid significantly changing the soil/solution ratio and decreasing the mass of solute available for desorption. A greater aliquot of 1 mL was taken and analyzed after 47 hours.
3.5.2	Test solution and Test conditions	Dinotefuran was tested in the following concentrations during the advanced test: 0.964, 0.243, 0.049, 0.024 and 0.010 mg/L. The amount of organic solvent (acetone) did not exceed 0.3% at the top concentration and 0.1% at the remaining concentrations.
3.6	**Test performance**	
3.6.1	Preliminary test	According to (a)"OECD 106": Yes
3.6.2	Screening test: Adsorption	According to (a)"OECD 106": Yes

3.6.3 Screening test: Desorption — According to (a)"OECD 106": Not performed

3.6.4 HPLC-method — According to (a)" OECD-HPLC-method": Not reported

HPLC performed on a ODS C18 column (250 × 4.6 mm, 5 µm), LiChrospher 100 C18 pre-column (4 × 4 mm, 5 µm) at room temperature. A gradient method with 10mM Octanesulfonic acid in water (solvent A) and methanol (solvent B) was used. Flow was 1.0 ml/min. UV detection at 220 nm, ^{14}C detection using Packard FLO-ONE.

3.6.5 Other test — Advanced test: adsorption isotherms and desorption kinetics/desorption isotherms

4 RESULTS

4.1 Preliminary test — See Table A7.1_3-2

4.2 Screening test: Adsorption — See Table A7.1_3-3

4.3 Screening test: Desorption — Not conducted

4.4 Calculations

Soil	loamy sand	silt loam	loam	sandy loam	clay loam
K_F	0.119	0.215	1.009	0.713	1.221
K_{Foc}	6	22	42	45	42
n	1.18	1.14	1.18	1.14	1.12
$K_{des,F}$	1.4	1.8	9.5	3.4	8.7
$K_{des,Foc}$	66	178	397	213	299
n	1.02	0.98	0.96	1.00	0.94

4.5 Degradation product(s) — Not reported

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

Guidelines:

OECD Guideline 106 (January 21, 2000), Annex, Revision 3 (draft) by the Food Agriculture Organization of United Nations (August 28, 1993), Commission Directive 95/36/EC (July 14, 1995), EPA OPP Guideline N-163-1

No relevant deviations from test guidelines.

Method:

In the preliminary test, the adsorption behavior of ^{14}C-dinotefuran was studied using three different soil dry weight to aqueous phase ratios. Two soil types (soil I and II) were tested in this portion of the study. Soil samples of 20 g, 4 g, and 1 g respectively, were shaken each with 20 mL of 0.01 M $CaCl_2$ solution, at the test concentration of 0.259 mg ^{14}C-dinotefuran/L. Soil/aqueous phase suspensions were incubated in sealed Teflon® centrifuge tubes on a shaker. Tubes were shaken at about 200 strokes per minute in the dark at 20 °C. Aliquots of the aqueous phase were analyzed by LSC after 2, 4, 24, and 48 hours of agitation. An additional analysis was made after 48 hours by HPLC.

In the screening test, the adsorption was studied in six different soil types by means of adsorption kinetics at a single concentration and determination of distribution coefficients k_d and K_{oc}. Based on the results of the preliminary test, the soil/solution ratio of 1/1, the weight of the soil sample (10 g), and the volume of the aqueous phase of 10 mL were chosen. Duplicate samples were set-up for each interval. In addition, duplicate control and blank samples were set up for each soil. Duplicate samples were analyzed by LSC after 2, 4, 24 and 48 hours of adsorption. An additional analysis was made after 48 hours by HPLC.

The distribution coefficients Kd at equilibrium as well as the organic carbon normalized adsorption coefficient Koc were calculated from the results obtained. A further mass balance was performed for 3 soils - loamy sand, silt loam and sand. After 48 hours of adsorption, the aqueous phase of each tube containing these soils was decanted and the remaining soil was extracted three times with 80% acetonitrile. Triplicate aliquots of the soil after extraction (about 0.5 g) were taken for combustion.

For the advanced test (adsorption isotherms and desorption kinetics/desorption isotherms) : with respect to the results obtained in the preliminary and screening tests, the study of the adsorptive behavior of ^{14}C-dinotefuran on soil and its potential mobility was continued by determining Freundlich adsorption isotherms.
In all tests the acetone was used as co-solvent. The concentration of organic solvent did generally not exceed 0.1%.

5.2 Results and discussion

An estimation of the Koc value as a function of the dinotefuran water solubility resulted in Koc values of between 13 and 58.

In the preliminary study, equilibrium was reached after approximately 24 to 48 hours for both soils. The percentage of the applied amount that was adsorbed after 48 hours depended on the relative amount of soil and increased with increasing soil to aqueous phase ratio. Loamy sand showed 13.1%, 3.6%, and 1.7% adsorption at the ratios 1/1, 1/5, and 1/20, respectively. For silt loam the corresponding values were 20.1%, 5.1%, and 1.7%.

The control samples showed no adsorption of the test item on the tube walls. Blank samples showed only background radioactivity. The pH of the aqueous phase was measured before and after contact with the soil. The measured pH was 5.4 for the aqueous phase before contact with the soil : 5.5 for loamy sand and 6.2 for silt loam after contact. The resulting Koc values (ration 1/1) for loamy sand and silt loam were 7 and 25 cm^3/g, respectively. The balance of the radioactivity applied was 95.2% and 96.9% for loamy sand and silt loam, respectively. In loamy sand, 86.9% of the radioactivity applied was detected in the supernatant. For silt loam, the amount detected was 79.9%. The extraction of the soil recovered 4.0% and 8.5% for loamy sand and silt loam, respectively, while unextracted radioactivity amounted to 4.3% and 8.6% of the initial amount applied.

Four additional soils (loam, sandy loam, clay loam and sand) were used for the succeeding screening test. The test was repeated for loamy sand and silt loam at the soil to aqueous phase ratio of 1/1 (10 g soil/10 mL solution). Sand soil was added to fulfill the EPA requirement to use a soil with an organic matter content of below 1.0. The test concentration was 0.46 (soils loam, sandy loam and clay loam) to 0.52 mg (soils loamy sand, silt loam and sand) ^{14}C-dinotefuran/L. Aliquots of the aqueous phase were analyzed by LSC after 2, 4, 24 and 48 hours of agitation. An additional analysis was made after 48 hours by HPLC.

Equilibrium time was reached after about 24 to 48 hours of adsorption under the same conditions as mentioned above.

The balance of the radioactivity applied was 99.5% for loamy sand, 99.8% for silt loam and 99.2% for sand. In the supernatant, amounts of 84.4%, 82.4%,and 96.0% of the radioactivity applied were detected for soils loamy sand, silt loam and sand, respectively. The extraction recovered was 11.9%, 11.1% and 2.1% for soils loamy sand, silt loam and sand, respectively. The direct combustion of the extracted soil recovered 3.1%, 6.3% and 1.1% for soils loamy sand, silt loam and sand, respectively.

Adsorption and desorption isotherms were determined in an advanced test on five soils (loamy sand, silt loam, loam, sandy loam and clay loam). Five concentrations were used: 0.964, 0.243, 0.049, 0.024 and 0.010 mg/L, covering two orders of magnitude. The soil/solution ratio of 1/1 was applied and the agitation time used was 47 hours. The desorption kinetics were performed for 4, 24, and 47 hours of shaking. Desorption isotherms were calculated for all soils from the values obtained after 47 hours of desorption

The calculated K_{des}foc values were much higher than those obtained for the adsorption isotherms, indicating the in part irreversibility of the adsorption. According to the classification system of McCall *et al.*, dinotefuran has a very high mobility in soils. X

5.2.1 Adsorbed a.s. [%] From the screening test, the percentage of the applied amount that was adsorbed after 48 hours was 63.1% for loam, 47.2% for sandy loam, 61.6% for clay loam and 4.3% for sand.

5.2.2 K_F See 4.4 Calculations above

5.2.3 K_{oc} See 4.4 Calculations above

5.2.4 $K_{des. F}$ See 4.4 Calculations above

5.2.5 $K_{des. oc}$ See 4.4 Calculations above

5.2.6 Degradation products (% of a.s.) Not reported

5.3 Conclusion An estimation of the dinotefuran Kfoc values in soil resulted in values between 6 - 42 with 1/n values ranging from 1.12 - 1.18 derived in the advanced test. Koc values derived in the screening test ranged between 9 - 71. X

The adsorption/desorption test performed on six soils (loamy sand, silt loam, loam, sandy loam, clay loam and sand) confirmed the estimated values. The test item was shown to be stable in the aqueous solution as well as in the soil/solution mixture during the test. In addition, the mass balance showed that no losses of radioactivity occurred. The adsorption and desorption kinetics indicated that equilibrium was reached after about 24 to 48 hours of agitation.

The calculated K_{des}oc values were higher than those obtained for the adsorption isotherms, indicating the in part irreversibility of the adsorption. According to the classification system found in the literature, dinotefuran has a very high mobility in soils. X

5.3.1 Reliability 1

Section A7.1.3 Adsorption / Desorption screening test

Annex Point IIA7.7

5.3.2 Deficiencies No

Table A7.1.3-1: Soil types and their characteristics

Parameters	**Soil 1**	**Soil 2**	**Soil 3**	**Soil 4**	**Soil 5**	**Soil 6**	**Soil 7**	**Soil 8**
Site location	Speyer 2.2	Senozan	Itingen	Speyer 2.3	US III	US I	Minnesota	Spra 02
Origin	Germany	France	Switzerland	Germany	USA	USA	USA	Spain
Batch	F2.22100	06/00	02/99	F2.31600	5783147	5783146	160	08/07/99
Soil type	Loamy sand	Silt loam	Clay	Sandy loam	Loam	Sandy loam	Clay loam	Sand
Particle size analysis (USDA):								
< 0.002 (clay) %	7.5	23.6	46.3	7.4	20	14	32.3	5.2
0.002 – 0.05 (silt) %	15.4	56.1	40.0	26.5	31	17	34.1	2.0
> 0.05 (sand) %	77.1	20.3	13.7	66.2	49	69	33.6	92.8
pH [0.01M $CaCl_2$)	5.7	5.8	7.0	6.5	6.2	5.8	5.7	7.5
Organic carbon [g/100 g soil] %	2.17	1.0	2.63	0.71	2.4	1.6	2.9	0.09
Cation exchange capacity [mmol/kg soil]	11	15.5	32.5	11	20.4	14.9	32.0	2.5
Carbonate as $CaCO_3$ [g/100 g soil]%	n.a.	< 0.30	16.10	n.a.	n.a.	n.a.	< 0.30	0.80
Nitrogen content %	0.26	0.11	0.27	0.06	0.11	0.14	0.3	0.02
Organic matter %	3.74	1.71	4.53	1.22	4.14	2.79	5.02	0.16
C/N-ratio	8.3	9.1	9.7	11.8	21.8	11.4	9.4	4.5

n.a.: not available

Data for soils 1 and 4 as obtained by Lufa (67346 Speyer, Germany); all others as determined by AgroLab (6031 Ebikon, Switzerland)

Table A7.1.3-2: Results of preliminary test: distribution of dinotefuran between aqueous phase and soil (1: Speyer 2.2, 2: Senozan) after adsorption at 3 different soil to aqueous phase ratios

Sample	Ratio	m [g]	V_0 [cm^3]	m(ads)s [µg]	m(ads)aq [µg]	Kd [cm^3/g]	Kd*ratio [cm^3/g]	Koc [cm^3/g]
Soil 1 (loamy sand)	1:1							
Sample A		20	20	0.69	4.5	0.154	0.15	7
Sample B		20	20	0.66	4.5	0.147	0.15	7
Mean					4.5	0.150	0.15	7
Soil 1 (loamy sand)	1:5							
Sample A		4	20	0.22	5.0	0.227	0.05	10
Sample B		4	20	0.15	5.0	0.152	0.03	7
Mean					5.0	0.189	0.04	9
Soil 1 (loamy sand)	1:20							
Sample A		1	20	0.13	5.1	0.506	0.03	23
Sample B		1	20	0.05	5.1	0.204	0.01	9
Mean					5.1	0.355	0.02	16
Soil 2 (silt loam)	1:1							
Sample A		20	20	1.1	4.1	0.264	0.26	26
Sample B		20	20	1.0	4.2	0.241	0.24	24
Mean					4.1	0.252	0.25	25
Soil 2 (silt loam)	1:5							
Sample A		4	20	0.2	4.9	0.243	0.05	24
Sample B		4	20	0.3	4.9	0.292	0.06	29
Mean					4.9	0.267	0.05	27
Soil 2 (silt loam)	1:20							
Sample A		1	20	0.1	5.1	0.315	0.02	32
Sample B		1	20	0.1	5.1	0.364	0.02	36
Mean					5.1	0.340	0.02	34

m = mass of soil (g)
V_0 = initial volume of the aqueous phase in contact with the soil (cm^3)
m(ads)s = mass of the test item adsorbed on the soil at adsorption equilibrium (µg)
m(ads)aq = mass of test item in the solution at adsorption equilibrium (µg)
Kd = distribution coefficient (cm^3/g)
Koc = distribution coefficient related to the organic carbon content of the soil (cm^3/g)

Table A7.1.3-3: Results of preliminary test: mass balance in percent of radioactivity applied for soil 1 (Speyer 2.2) and soil 2 (Senozan)

Sample	Ratio	mass applied [µg]	(ads)aq [%]	(ads)extract [%]	(ads)residue [%]	recovery [%]
Soil 1 (loamy sand)	1:1					
Sample A		5.2	86.7	5.6	4.3	96.5
Sample B		5.2	87.2	2.5	4.3	94.0
Mean			86.9	4.0	4.3	95.2
Soil 2 (silt loam)	1:1					
Sample A		5.2	79.1	8.1	9.5	96.8
Sample B		5.2	80.6	8.8	7.7	97.1
Mean			79.9	8.5	8.6	96.9

(ads)aq : percent of the amount applied remaining in the aqueous phase
(ads)extract : percent of the amount applied being extracted after the adsorption step
(ads)residue : percent of the amount applied remaining unextracted in the soil

Table A7.1.3-4: Results of screening test: distribution of dinotefuran between aqueous phase and soil after adsorption to six different soils

Sample	Ratio	m [g]	V_0 [cm^3]	m(ads)s [µg]	m(ads)aq [µg]	Kd [cm^3/g]	Kd*ratio [cm^3/g]	Koc [cm^3/g]
Soil 1 (loamy sand)	1:1							
Sample A		10	10	0.85	4.3	0.196	0.20	9
Sample B		10	10	0.79	4.4	0.180	0.18	8
Mean					4.4	0.188	0.19	9
Soil 2 (silt loam)	1:1							
Sample A		10	10	0.89	4.3	0.207	0.21	21
Sample B		10	10	0.97	4.2	0.229	0.23	23
Mean						0.218	0.22	22
Soil 5 (loam)	1:1							
Sample A		10	10	3.0	1.7	1.752	1.75	73
Sample B		10	10	2.9	1.7	1.664	1.66	69
Mean					1.7	1.708	1.71	71
Soil 6 (sandy loam)	1:1							
Sample A		10	10	2.2	2.5	0.868	0.87	54
Sample B		10	10	2.2	2.4	0.918	0.92	57
Mean					2.4	0.893	0.89	56
Soil 7 (clay loam)	1:1							
Sample A		10	10	2.9	2.3	1.235	1.24	43
Sample B		10	10	2.8	2.3	1.223	1.22	42
Mean					2.3	1.229	1.23	42
Soil 8 (sand)	1:1							
Sample A		10	10	0.2	5.0	0.046	0.05	51
Sample B		10	10	0.2	5.0	0.043	0.04	48
Mean					5.0	0.044	0.04	49

m = mass of soil (g) ; V_0 = initial volume of the aqueous phase in contact with the soil (cm^3)
m(ads)s = mass of the test item adsorbed on the soil at adsorption equilibrium (µg)
m(ads)aq = mass of test item in the solution at adsorption equilibrium (µg)
Kd = distribution coefficient (cm^3/g) ; Koc = distribution coefficient related to the organic carbon content of the soil (cm^3/g)

Table A7.1.3-5 Results of advanced test: distribution of ^{14}C-dinotefuran between aqueous phase and soil after desorption. Evaluation according to the Freundlich desorption isotherms

	Soil 1 (loamy sand)				
Concentration Ci (µg/cm^3)	**0.964**	**0.243**	**0.049**	**0.024**	**0.010**
m(des)s (µg)					
Sample A	0.47	0.26	0.06	0.02	0.01
Sample B	0.54	0.24	0.06	0.02	0.01
Mean (µg)	0.51	0.25	0.06	0.02	0.01
Mean (% of applied)	5.27	10.32	11.92	9.94	11.45
m(des)s / m(soil) (µg/g)	0.051	0.025	0.006	0.002	0.001
log(m(des)s / m(soil))	-1.294	-1.601	-2.235	-2.621	-2.959
c(des)aq (µg/cm^3)	0.035	0.015	0.003	0.002	0.001
log(c(des)aq)	-1.456	-1.820	-2.483	-2.784	-3.192

	Soil 2 (silt loam)				
Concentration Ci (µg/cm^3)	**0.964**	**0.243**	**0.049**	**0.024**	**0.010**
m(des)s (µg)					
Sample A	0.98	0.38	0.08	0.04	0.02
Sample B	0.93	0.35	0.08	0.03	0.01
Mean (µg)	0.95	0.36	0.08	0.04	0.02
Mean (% of applied)	9.88	14.92	16.77	14.95	15.75
m(des)s / m(soil) (µg/g)	0.095	0.036	0.008	0.004	0.002
log(m(des)s / m(soil))	-1.021	-1.441	-2.087	-2.443	-2.820
c(des)aq (µg/cm^3)	0.061	0.021	0.005	0.002	0.001
log(c(des)aq)	-1.213	-1.687	-2.335	-2.612	-2.993

	Soil 5 (loam)				
Concentration Ci (µg/cm^3)	**0.964**	**0.243**	**0.049**	**0.024**	**0.010**
m(des)s (µg)					
Sample A	4.60	1.24	0.26	0.15	0.06
Sample B	4.68	1.30	0.28	0.15	0.06
Mean (µg)	4.64	1.27	0.27	0.15	0.06
Mean (% of applied)	48.13	52.36	55.00	63.70	61.82
m(des)s / m(soil) (µg/g)	0.464	0.127	0.027	0.015	0.006
log(m(des)s / m(soil))	-0.334	-0.896	-1.571	-1.814	-2.226
c(des)aq (µg/cm^3)	0.047	0.016	0.005	0.002	0.001
log(c(des)aq)	-1.328	-1.785	-2.315	-2.720	-3.132

Ci = initial concentration in the supernatant before adsorption (µg/cm^3)
m(des)s = mass of the test item remaining adsorbed on the soil at desorption equilibrium (µg)
m = mass of soil (1 g)
c(des)aq = concentration of test item in the solution at desorption equilibrium (µg/cm^3)

Table A7.1.3-5 (continued) Results of advanced test: distribution of ^{14}C-dinotefuran between aqueous phase and soil after desorption. Evaluation according to the Freundlich desorption isotherms

	Soil 6 (sandy loam)				
Concentration Ci (µg/cm^3)	**0.964**	**0.243**	**0.049**	**0.024**	**0.010**
m(des)s (µg)					
Sample A	3.12	0.96	0.20	0.10	0.04
Sample B	3.02	0.96	0.21	0.10	0.04
Mean (µg)	3.07	0.96	0.20	0.10	0.04
Mean (% of applied)	31.85	39.64	41.92	42.75	44.44
m(des)s / m(soil) (µg/g)	0.307	0.096	0.020	0.010	0.004
log(m(des)s / m(soil))	-0.513	-1.017	-1.689	-1.987	-2.370
c(des)aq (µg/cm^3)	0.093	0.026	0.006	0.003	0.001
log(c(des)aq)	-1.033	-1.591	-2.208	-2.531	-2.917

	Soil 7 (clay loam)				
Concentration Ci (µg/cm^3)	**0.964**	**0.243**	**0.049**	**0.024**	**0.010**
m(des)s (µg)					
Sample A	4.74	1.31	0.28	0.14	0.06
Sample B	4.74	1.32	0.28	0.14	0.06
Mean (µg)	4.74	1.31	0.28	0.14	0.06
Mean (% of applied)	49.15	54.17	57.19	56.56	58.20
m(des)s / m(soil) (µg/g)	0.474	0.131	0.028	0.014	0.006
log(m(des)s / m(soil))	-0.324	-0.881	-1.555	-1.865	-2.252
c(des)aq (µg/cm^3)	0.058	0.022	0.005	0.002	0.001
log(c(des)aq)	-1.240	-1.659	-2.302	-2.607	-3.040

Ci = initial concentration in the supernatant before adsorption (µg/cm^3)
m(des)s = mass of the test item remaining adsorbed on the soil at desorption equilibrium (µg)
m = mass of soil (1 g)
c(des)aq = concentration of test item in the solution at desorption equilibrium (µg/cm^3)

	Evaluation by Competent Authorities
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	10 July 2012
Materials and Methods	The Applicant's version is considered to be acceptable, noting the following :- **3.1** : Test material is technical grade dinotefuran supplied under its code name of MTI-446.
Results and discussion	The Applicant's version is considered to be acceptable, noting the following :- **5.2 & 5.3** : It is noted that based upon the classification system developed by McCall et al (1980) using K_{oc} values derived in this study, dinotefuran could be considered to be very highly mobile (mean K_{oc} <50 in all but one soil type : loam). However, whilst this system is not used under BPD, it is clear that the compound has the potential to be very mobile in soil. **5.3** : It should be noted that K_{oc} values determined in the advanced test actually ranged between 6 – 45 with an arithmetic mean of 31.4 (where n=5). In the screening test, K_{oc} values ranged from 9 - 71 and gave rise an arithmetic mean of 41.5 (where n=6).
Conclusion	The Applicant's version is considered to be acceptable.
Reliability	Accepted as being 1
Acceptability	The Applicant's version is considered to be acceptable.
Remarks	Results from the preliminary test, screening test and advanced test indicate that dinotefuran has the potential to be mobile in 6 different soil types, with mean K_{oc} values ranging from 9 – 71 (screening test) to 6 – 45 (advanced test). Arithmetic mean K_{oc} based on 5 soil samples in the advanced test was determined as 31.4.
	COMMENTS FROM ...
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

Section 7.1.4.1 **Annex Point IIIA, XII.2.1**	**Field study on accumulation in the sediment**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	**Official use only**
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [X]** **Other justification [ ]**	
Detailed justification:	A field study on accumulation in the sediment should be done when non-extractable residues are formed exceeding 70% of the initial dose in the water/sediment study or if the mineralization rate in the water/sediment system is less than 5% in 100 days. On 103-day, non-extractable residue is 24.3% river system and 25.4% pond system; mineralization ($^{14}CO_2$) is 14.8% river system and 7.3% pond system. Therefore this study is not required. See Section A7.1.2.2.2.	
Undertaking of intended data submission [ ]	Not applicable	

	Evaluation by Competent Authorities
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	16 January 2013
Evaluation of applicant's justification	As indicated, results from a water/sediment degradation study (performed in accordance with appropriate EC / EPA methodology) indicate that non-extractable residues in sediment only reached a maximum of 62.9% AR on study completion (day 320) in the pond system and a maximum of 29.5% AR on day 141 in the river system. Furthermore, mineralisation exceeded 5% on day 103 in both test systems (7.3% for pond and 14.8% for river).
Conclusion	The Applicant's justification is considered to be acceptable.
Remarks	None
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	
Evaluation of applicant's justification	
Conclusion	
Remarks	

Section 7.1.4. Annex Point IIIA, XII.2.2	**Further studies on adsorption and desorption in water/sediment systems and, where relevant, on the adsorption and desorption of metabolites and degradation products where the preliminary risk assessment indicates that it is necessary**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	**Official use only**
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [X]** **Other justification [ ]**	
Detailed justification:	Further studies on adsorption and desorption in water/sediment systems and, where relevant, on the adsorption and desorption of metabolites and degradation products are required where the preliminary risk assessment indicates that it is necessary. Therefore this study is not required. See Section A7.1.2.2.2.	
Undertaking of intended data submission [ ]	Not applicable	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	16 January 2013	
Evaluation of applicant's justification	Due to the restricted indoor use pattern of the representative product (cockroach gel bait), the ESD for PT 18 predicts limited emissions to local STP based on a maximum cleaning efficiency of 3%. Surface waters will only be indirectly exposed to dinotefuran via discharge of STP effluent. It should be noted that the Applicant has submitted data on water-sediment degradation (provided in **A7.1.2.2.2**) plus adsorption / desorption to organic matter in soil (provided in **A7.1.3**) as a means of refinement in risk assessment.	
Conclusion	The Applicant's justification is considered to be acceptable.	
Remarks	None	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date		
Evaluation of applicant's justification		
Conclusion		
Remarks		

Section A7.2.1-1 Aerobic degradation in soil, initial study

Annex Point VII 4, XII.1.1

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1 REFERENCE

1.1	**Reference**	Völkl S., 2003a, ^{14}C-MTI-446 : Metabolism in one soil incubated under aerobic conditions. RCC Ltd, Itingen, Switzerland; unpublished report no. 843175, August 18, 2003.
1.2	**Data protection**	Yes
1.2.1	Data owner	Mitsui Chemicals Agro, Inc.
1.2.2	Criteria for data protection	Data on new a.s. for first entry to Annex I

2 GUIDELINES AND QUALITY ASSURANCE

2.1	**Guideline study**	Yes Commission Directive 95/36/EC of 14 July 1995 amending Council Directive 91/414/EEC: Annex II: 7.1.1.2 laboratory studies – aerobic degradation. SETAC Europe: Procedures for assessing the environmental fate and ecotoxicity of pesticides, March 1995, Part 1 – Aerobic degradation OECD Guidelines for testing chemicals: Aerobic – Anaerobic transformation in soil (Draft proposal, August 2000)
2.2	**GLP**	Yes
2.3	**Deviations**	No

3 MATERIALS AND METHODS

3.1	**Test material**	Dinotefuran (non-labelled and ^{14}C labelled) supplied as MTI-446
3.1.1	Lot/Batch number	Non-labelled test item : EBI-5-101 Labelled test item: Batch No. CP-2499 (G-label) and CP-2498 (F-label) mixed in equal amounts
3.1.2	Specification	As given in section 2 (namely Doc III-A.2)
3.1.3	Purity	Non-labelled test item: 99.6% by HPLC Labelled test item: 96.6% (radiochemical purity)
3.1.4	Radiolabelling	G-label (guanidine side chain label), F-label (furanyl ring label)
3.1.5	Further relevant properties	Melting point: 107.5 °C Vapour pressure at 30 °C: $< 1.7 \times 10^{-6}$ Pa Solubility in water at 20 °C: 39.83 g/L
3.1.6	TS inhibitory to microorganisms	No
3.1.7	Analytical methods	TLC was used to quantify the ^{14}C-dinotefuran in the extracted soil samples, while HPLC analysis was used to confirm the results obtained by TLC. LSC was used for radioactivity quantification.
3.2	**Transformation products**	Yes Main transformation products characterised as MNG (i.e. 1-methyl-2-nitroguanidine) and NG (i.e. nitroguanidine). Up to nine degradation products were detected in the soil extracts.

Section A7.2.1-1 Aerobic degradation in soil, initial study

Annex Point VII 4, XII.1.1

3.2.1	Method of analysis for transformation products	Characterisation by HPLC and TLC co-chromatography with reference standard	
3.3	**Reference substance**	No	
3.4	**Testing procedure**		
3.4.1	Soils	See Table A7.2.1.1-1	
3.4.2	Test system	See Table A7.2.1.1-2	X
3.4.3	Test conditions	See Table A7.2.1.1-3	
3.4.4	Method of preparation of test solution	Initial concentrate solutions of both radiolabelled compounds were prepared in acetone. Aliquots of both concentrates were taken, the solvent evaporated and re-dissolved in purified water. The final dosing solution was prepared with aliquots of the stock solutions prepared with the F-label and G-label.	
3.4.5	Initial TS concentration	0.03 mg/ 100 g (i.e. 0.3 mg / kg dry soil for MTI-446)	
3.4.6	Duration of test	120 days	
3.4.7	Analytical extraction procedure and sample preparation	The soils were extracted up to four times with acetonitrile:water (8:2 v/v) followed by a Soxhlet extraction acetonitrile:water (8:2 v/v) in all samples except days 0. The extracts were combined and quantified by LSC, concentrated under reduced pressure at 30°C and analysed by HPLC or TLC. After extraction, the soils were dried, weighed, homogenised and combusted for determination of their radioactivity by LSC. Aliquots of the extracted soils on day 120 were subject to a harsh extraction under reflux with acetonitrile/0.1M HCl (1:1 v/v). On these samples, an additional organic matter fractionation was applied by extraction with NaOH and precipitation with HCl. Volatile radioactivity was trapped during the study with NaOH traps (CO_2) and ethylene glycol (organic volatiles). These solutions were then analysed by LSC.	
3.4.8	Sampling	Immediately after application and after 3, 7, 10, 14, 21, 28, 62 and 120 days of incubation, one sample of each system was taken for analysis. On day 0 and 28, duplicate samples were analysed from the 20 °C test system.	
3.4.9	Intermediates/ degradation products	Chromatographic analysis for characterisation of degradation products and quantification of the parent compound was as follows: TLC method: 1 and 2 dimensional chromatography performed on silica gel 60 F_{254} plates, (5×20 cm or 20×20 cm, 0.25 mm thickness) without chamber saturation. A variety of 4 solvent systems was used. UV detection at 254 nm. Radiolabelled detection with a phosphor imager. HPLC method: Pre-column, LiChrospher C18 (4 mm × 4 mm, 5µm) Column,	

Section A7.2.1-1 Aerobic degradation in soil, initial study

Annex Point VII 4, XII.1.1

Phenomenex Luna C8 (250 mm × 4.6 mm, 5µm), gradient method with 4.5M ammonium hydroxide + 5mM nonafluorovaleric acid in water (solvent A) and 5mM nonafluorovaleric acid in methanol (Solvent B) or 10 mM octanesulfonic acid in water (solvent A) and methanol (Solvent B), at room temperature and a 1 mL/minute flow rate. UV detection at 220 nm plus ^{14}C detection with a liquid scintillant cell.

3.4.10 Microbial biomass measurement

Yes

Microbial biomass was determined at the start and end of the test by a modification of the respiratory method.

3.4.11 Controls

No controls were used other than for microbial biomass.

3.4.12 Statistics

DT_{50} and DT_{90} degradation kinetics were calculated with the MicroCal Origin v3.5 program. First order kinetics were applied.

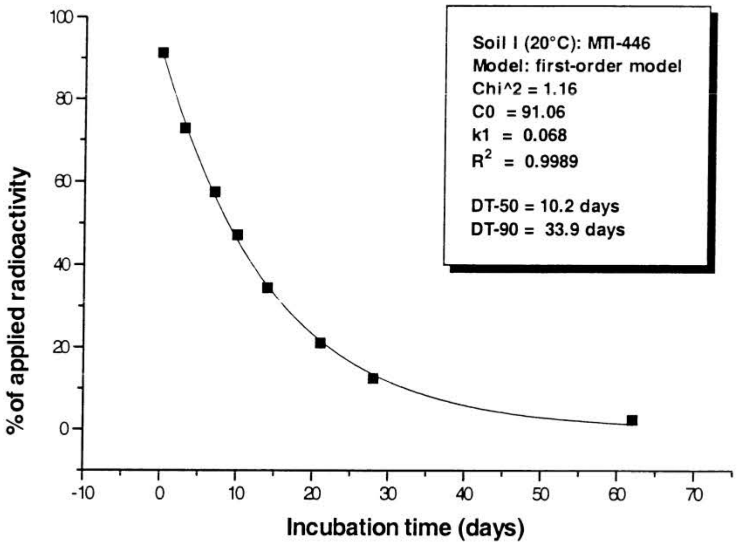
4 RESULTS

4.1 Degradation of test substance

4.1.1 Graph

Dinotefuran 20°C

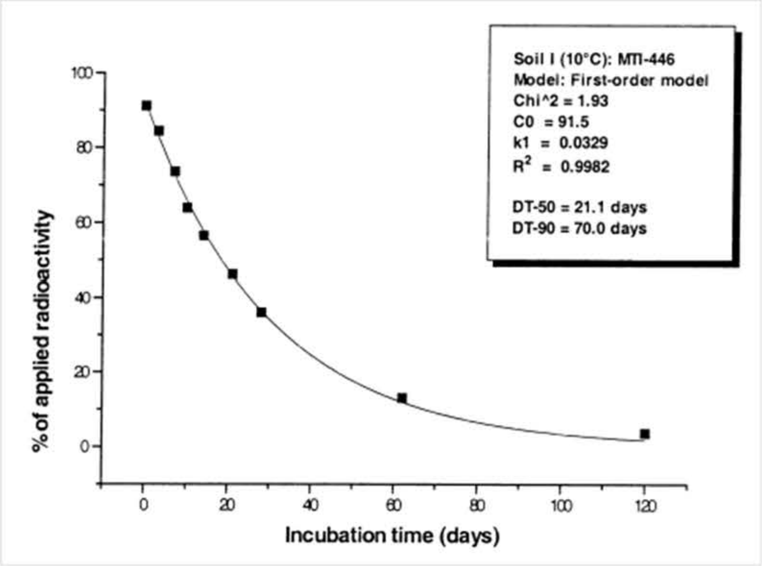
X



Section A7.2.1-1 Aerobic degradation in soil, initial study

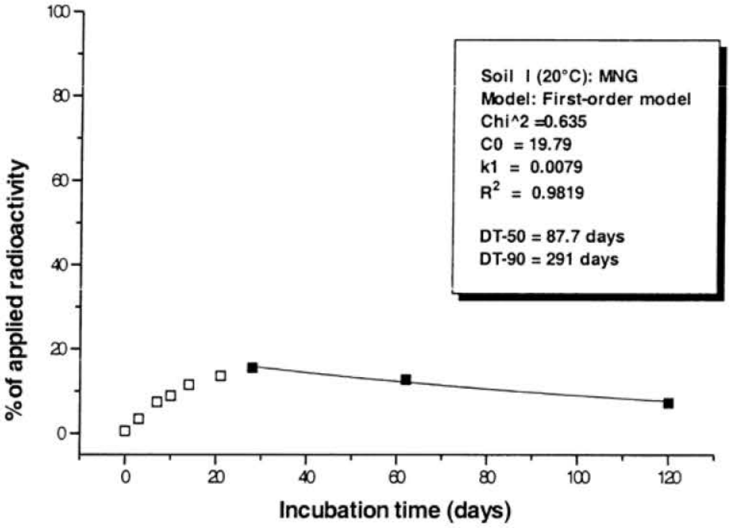
Annex Point VII 4, XII.1.1

Dinotefuran 10°C



X

Methyl nitroguanidine



X

4.1.2 Degradation

In the experiment, total recoveries of radioactivity (mass balances) were 93.5±1.8% applied radioactivity (AR) for the 20°C system and 93.5±2.4% for the 10°C system. Total extractable radioactivity declined rapidly from 94.1% on day 0 to 13.3% AR on day 120 in the 20°C system, and from 94.1% to 26.4% AR in the 10°C system. There were corresponding increases with time in non-extractable radioactivity with maxima of 25.7% AR in the 20°C system and 19.9% in the 10°C system. Organic matter fractionation indicated that the non-extractable radioactivity was mainly bound to the immobile humic acids and humic fraction. Volatile radioactivity, all associated with $^{14}CO_2$, represented a maximum of 52.1% AR in the 20°C system and 43.7% AR in the 20°C system.

DT_{50} values were calculated as follows:

	Aerobic DT_{50} [days]	
	20°C	10°C
Dinotefuran		
DT_{50}	10.2	21.1
DT_{90}	33.9	70.0
MNG		
DT_{50}	87.7	-
DT_{90}	291	-

X

A summary of the results is given in tabular form in Table A7.2.1.1-4 and A7.2.1.1-5.

4.1.3 Other observations

The microbial biomass stayed constant throughout the study

4.1.4 Degradation of TS in abiotic control

No abiotic control used

4.1.5 Degradation of reference substance

No reference substance used

4.1.6 Intermediates/ degradation products

Dinotefuran mainly degraded to MNG reaching a maximum amount of 15.6% (day 28) and 16.0% AR (day 62) in the 20°C and 10°C system, respectively. Additionally NG reached 5% AR on day 120 in the 10°C system and on day 62 in the 20°C system. Up to 9 minor degradation products were detected. Ultimate degradation to CO_2 was significant reaching a maximum of 52.1% and 43.7% AR in the 20°C and 10°C system, respectively. A half life for the degradation product MNG could only be calculated at the higher temperature.

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

Degradation in water/sediment systems was studied according to the SETAC Europe: Procedures for assessing the environmental fate and ecotoxiciy of pesticides, March 1995, Part 1 – Aerobic degradation and OECD Guidelines for testing chemicals: Aerobic – Anaerobic transformation in soil (Draft proposal, August 2000). No deviations were observed.

5.2 Results and discussion

The degradation of dinotefuran in soil under aerobic conditions was studied with ^{14}C labelled test substance in two different labels. Two soil systems were set up at 10°C and 20°C.

In the experiment, total recoveries of radioactivity (mass balances) were generally 93.5±1.8% applied radioactivity (AR) for the 20°C system and 93.5±2.4% for the 10°C system. Total extractable radioactivity declined rapidly from 94.1% on day 0 to 13.3% AR on day 120 in the 20°C system, and from 94.1% to 26.4% AR in the 10°C system. There were corresponding increases with time in non-extractable radioactivity with maxima of 25.7% AR in the 20°C system and 19.9% in the 10°C system. Organic matter fractionation indicated that the non-extractable radioactivity was mainly bound to the immobile humic acids and humic fraction. Volatile radioactivity, all associated with $^{14}CO_2$, represented a maximum of 52.1% AR in the 20°C system and 43.7% AR in the 10°C system after 120 d. Dinotefuran mainly degraded to MNG reaching a maximum amount of 15.6% AR (day 28) and 16.0% AR (day 62) in the 20°C and 10°C systems respectively. Additionally, a further metabolite, NG, reached 5.4% AR on day 120 in the 10°C system and 5.2% AR on day 62 in the 20°C system. Up to 9 minor degradation products were also detected. Ultimate degradation to CO_2 was significant, reaching a maximum amount at study completion of 52.1% and 43.7% AR in the 20°C and 10°C system respectively. A degradation half-life for the degradation product MNG could be calculated at 20 °C. **X**

5.3 Conclusion

Dinotefuran declined in aerobic soil systems with DT_{50} values of 10.2 d and 21.1 d (for the 20°C and 10°C systems respectively). One major degradation product (MNG) was formed, which accounted for a maximum of 15.6% of the applied radioactivity (on day 28) at 20°C. A DT_{50} value of 87.7 days was calculated for MNG in this test system.

NG accounted for up to 5.4% of the applied radioactivity but only exceeded 4.5% on one occasion at each temperature (10 °C and 20 °C).

5.3.1 Reliability 1

5.3.2 Deficiencies

No, however only single samples were taken on all sampling points except day 0 and day 28 at 20°C. Since these replicated well, and the tests at 10 °C and 20°C show a similar picture this fact does not affect the quality of the study. **X**

Table A7.2.1.1-1: Soil types and their characteristics

Parameters	System 1
Site location	Gartenacker, Switzerland
Batch No.	04/02
Particle size analysis (USDA):	SILT LOAM
< 0.002 (clay) %	10.3
0.002 – 0.05 (silt) %	52.3
> 0.05 (sand) %	37.4
pH [0.01M $CaCl_2$)	7.2
Organic carbon [g/100 g soil]	1.8
Cation exchange capacity [meq/100 g soil]	13.1
Maximum water holding capacity at pF1 [g/100g wet soil]	67.5
40% MWC [g/100g wet soil]	27.0

Table A7.2.1.1-2: Test system

Criteria	Details		
Vessel type	Glass metabolism flasks connected to a adsorption traps with NaOH and ethylene glycol		
Vessel replicates			
Number of vessels	Test	Treatment rate [mg/100 g]	Radiolabel
11	Aerobic 20°C	0.03	Mixture of F and G
11	Aerobic 10°C	0.03	Mixture of F and G
2	Microbial biomass control	-	-

Table A7.2.1.1-3: Test conditions

Parameters	
Test temperature [°C]	20 ± 2 and 10 ± 2
Light conditions	dark
Soil weight [g]	100
Depth of soil layer [cm]	2
Soil moisture	40% MWC
Aeration	Humidified air
Microbial biomass start of incubation [mg microbial C/100 g dry soil]	30.3
Microbial biomass end of incubation 20 °C [mg microbial C/100 g dry soil]	27.4
Microbial biomass end of incubation 10 °C [mg microbial C/100 g dry soil]	32.5

Table A7.2.1.1-4: Distribution and recovery of radioactivity in the 20 °C system [based on % AR]

Sample	Time after application [days]								
	0	3	7	10	14	21	28	62	120
Extractables	94.1	82.6	69.5	61.7	51.9	41.0	34.3	21.9	13.3
Non-extractables	1.9	5.9	8.9	11.9	13.6	16.1	17.8	20.9	25.7
Organic volatiles	-	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1
CO_2	-	6.5	15.9	21.4	27.6	35.1	39.8	49.3	52.1
Total AR recovery	95.9	95.0	94.3	95.0	93.1	92.2	91.9	92.1	91.0
Identified as parent	91.2	72.9	57.4	47.2	34.4	21.1	12.5	2.4	0.6
Identified as MNG	0.6	3.5	7.4	8.9	11.5	13.6	15.6	12.8	7.3
Identified as NG	n.d.	0.2	1.0	1.2	2.0	3.2	3.6	5.2	4.3

n.d. not detected or below limit of quantification
MNG: l-methyl-2-nitroguanidine
NG: nitroguanidine
Minor degradation products are not listed in the table

Table A7.2.1.1-5: Distribution and recovery of radioactivity in the 10 °C system [based on % AR]

Sample	Time after application [days]								
	0	3	7	10	14	21	28	62	120
Extractables	94.1	89.2	81.9	75.6	70.0	61.7	54.6	36.1	26.4
Non-extractables	1.9	3.9	6.0	7.4	8.3	10.1	12.2	16.6	19.9
Organic volatiles	-	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1
CO_2	-	3.0	7.3	11.2	12.0	21.8	26.7	37.5	43.7
Total AR recovery	95.9	96.1	95.2	94.1	90.3	93.6	93.4	90.3	90.1
Identified as parent	91.2	84.4	73.6	64.0	56.5	46.2	36.1	13.1	3.7
Identified as MNG	0.6	1.6	4.1	5.6	7.5	9.5	12.4	16.0	14.9
Identified as NG	n.d.	n.d.	0.3	0.5	0.6	1.5	1.6	3.8	5.4

n.d. not detected or below limit of quantification
MNG: l-methyl-2-nitroguanidine
NG: nitroguanidine
Minor degradation products are not listed in the table

Evaluation by Competent Authorities

EVALUATION BY RAPPORTEUR MEMBER STATE

Date	24 October 2012
Materials and Methods	The Applicant's version is considered to be acceptable noting the following :- **3.4.2** It should be noted that the number of sampling points in the 10 °C test system was not 11 as stated in **Table A7.2.1.1-2** but only 8 (namely 3, 7, 10, 14, 21, 28, 62 and 120 d) . At 20 °C, it is noted by UK CA that sampling was performed at 0, 3, 7, 10, 14, 21, 28, 62 and 120 d with duplicate samplings on day 0 and day 28 only (11 in total). Furthermore, the initial (day 0) duplicate samples taken at 20 ° C were used to support the 10 °C test.
Results and discussion	The Applicant's version is considered to be acceptable noting the following :- **4.1.1 & 4.1.2** The UK CA has repeated SFO kinetic modelling of results for degradation of dinotefuran in aerobic soil and can confirm the DT$_{50}$, k1 and r2 values obtained at each temperature (10 °C and 20 °C). When results at 20 °C for parent and metabolite are modelled together using SFO kinetics, DT$_{50}$ values slightly decrease to 10.14 d with r^2 of 0.999 (dinotefuran) and 72.4 d with r^2 of 0.99 (MNG) where the fraction of parent transformed was calculated as 22.4%. Therefore, in terms of risk assessment, it is proposed to use revised UK CA DT$_{50}$ values derived at 20 °C and corrected to average EU outdoor temperature. As an aside, the UK CA also modelled degradation of both compounds together at 10 °C and obtained DT$_{50}$ values of 21.07 d (r^2 of 0.998) for dinotefuran and 202.6 d (r^2 of 0.996) for MNG with 22.8% transformation of parent.
Conclusion	The Applicant's version is considered to be acceptable noting the following :- **5.2** The study report indicates that, besides the test item, 9 degradation products were detected in total. MNG was identified as the main (and sole major) degradation product as levels of NG only just exceeded 5% of AR on one occasion at each temperature. Although UF, FNG and five unknown radioactive fractions were detected in test systems, they were all present at low concentrations and can be considered to be of minor importance. **5.3.2** Test guidelines for OECD 307 (adopted April 2002) do indicate that well designed studies are considered to include sufficient flasks so that two may be sacrificed at each of at least 5 sampling events. Whilst duplicate samples were not taken at all 9 sampling points of the 20 °C test, there is good conformity between sampling results where they have been taken and recovery of AR has been ≥91% for all samples. Therefore, the argument presented by the Applicant that these equate to minor deviations and minor methodological deficiencies that do not affect quality of the results can be supported. No reduction in reliability scoring seems necessary and results can be used where relevant for risk assessment purposes.
Reliability	Reliability to remain as 1.
Acceptability	The Applicant's version is considered to be acceptable.
Remarks	Based on good visual fits for the degradation curves of dinotefuran at both 10 °C and 20 °C, it does appear that degradation of the compound can be represented by first order kinetics. Degradation of MNG has been more difficult to quantify due to limited data points and low reported concentrations (based on AR) in the study. The study does demonstrate almost complete removal of dinotefuran from the test system at both 20 °C and 10 °C after 120 d with significant levels of mineralisation based on CO$_2$ formation (>50% at 20 °C and >40% at 10 °C by study completion).

COMMENTS FROM...

Date

Materials and Methods

Results and discussion

Conclusion

Reliability

Acceptability

Remarks

Section A7.2.1-2 Anaerobic degradation in soil, initial study

Annex Point VII 4, XII.1.1

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1 REFERENCE

1.1	**Reference**	Völkl S., 2003b, ^{14}C-MTI-446 : Anaerobic soil degradation and metabolism. RCC Ltd, Itingen, Switzerland; unpublished report no. 841703, February 11, 2003.
1.2	**Data protection**	Yes
1.2.1	Data owner	Mitsui Chemicals Agro, Inc.
1.2.2	Criteria for data protection	Data on new a.s. for first entry to Annex I

2 GUIDELINES AND QUALITY ASSURANCE

2.1	**Guideline study**	Yes Commission Directive 95/36/EC of 14 July 1995 amending Council Directive 91/414/EEC: Annex I: 7.1.1.2 rate of degradation; 7.1.1.1.2 anaerobic degradation study. SETAC Europe: Procedures for assessing the environmental fate and ecotoxicity of pesticides, March 1995, Part 1 –2 Anaerobic degradation EPA 540/9-82-021; Section N-162-2 Anaerobic soil metabolism studies
2.2	**GLP**	Yes
2.3	**Deviations**	No

3 MATERIALS AND METHODS

3.1	**Test material**	Dinotefuran (non-labelled and ^{14}C labelled) supplied as MTI-446
3.1.1	Lot/Batch number	Non-labelled: EBI-5-101 Labelled test item: Batch No. CP-2499 (G-label) and CP-2498 (F-label) mixed in equal amounts
3.1.2	Specification	As given in section 2 (namely Doc III-A.2)
3.1.3	Purity	Non-labelled: 99.6% by HPLC Labelled test item: 96.9% (radiochemical purity)
3.1.4	Radiolabelling	G-label (guanidine side chain label), F-label (furanyl ring label)
3.1.5	Further relevant properties	Melting point: 107.5 °C Vapour pressure at 30 °C: $< 1.7 \times 10^{-6}$ Pa Solubility in water at 20 °C: 39.83 g/L
3.1.6	TS inhibitory to microorganisms	No
3.1.7	Analytical methods	HPLC was used to quantify the ^{14}C-dinotefuran in the extracted soil samples, whilst TLC analysis was used to confirm the results obtained by HPLC. LSC was used for radioactivity quantification.

3.2	**Transformation products**	Yes Main transformation products characterised as 1-methyl-3-(tetrahydro-3-furylmethyl)guanidine (DN) and 1-methyl-3-(tetrahydro-3-furylmethyl) urea (UF). Other minor metabolites were observed.	
3.2.1	Method of analysis for transformation products	Characterisation by HPLC and TLC co-chromatography with reference standard	
3.3	**Reference substance**	No	
3.4	**Testing procedure**		
3.4.1	Soils	See table A7.2.1.2-1	
3.4.2	Test system	See table A7.2.1.2-2	
3.4.3	Test conditions	See table A7.2.1.2-3	
3.4.4	Method of preparation of test solution	Initial concentrate solutions of both radiolabelled compounds were prepared in acetone. Aliquots of both concentrates were taken, the solvent evaporated and re-dissolved in purified water. The final dosing solution was prepared with aliquots of the stock solutions prepared with the F-label and G-label.	
3.4.5	Initial TS concentration	0.031 mg/100 g dry soil (i.e. 0.31 mg / kg dw soil)	
3.4.6	Duration of test	120 days	
3.4.7	Analytical extraction procedure and sample preparation	At each sampling point, the supernatant water was removed from the soil. The radioactivity in the water was directly measured by LSC. After concentration by rotary evaporation, the samples were directly analysed by HPLC and/or TLC. The soils were extracted up to three times with acetonitrile:water (8:2 v/v) followed by a Soxhlet extraction acetonitrile:water (8:2 v/v) in all samples from day 14 onwards. The extracts were combined and quantified by LSC, concentrated under reduced pressure at 30°C, diluted with acetonitrile and analysed by HPLC and/or TLC. After the extraction the soils were dried, weighed, homogenised and combusted for determination of their radioactivity by LSC. Aliquots of the extracted soils of day 120 were subject to a harsh extraction under reflux with acetonitrile/0.1M HCl (1:1 v/v). On these samples, an additional organic matter fractionation by extraction with NaOH and precipitation with HCl. Volatile radioactivity was trapped during the study with NaOH traps (CO_2) and ethylene glycol (organic volatiles). These solutions were then analysed by LSC.	
3.4.8	Sampling	Immediately after application and after 3, 7, 10, 14, 28, 59 and 120 days of incubation, one sample of each system was taken for analysis. On day 0 and 120, duplicate samples were analysed.	**X**
3.4.9	Intermediates/ degradation	Chromatographic analysis for characterisation of degradation products and quantification of the parent compound was as follows:	

	products	TLC method: One dimensional chromatography performed on silica gel 60 F_{254} or RP-18 plates, (5×20 cm, 0.25 mm thickness) without chamber saturation. A variety of 4 solvent systems was used. UV detection at 254 nm. Radiolabelled detection with a linear analyser. HPLC method: Pre-column, LiChrospher C18 (4 mm × 4 mm, 5µm) Column, Phenomenex Luna C8 (250 mm × 4.6 mm, 5µm), gradient method with 4.5M ammonium hydroxide + 5mM nonafluorovaleric acid in water (solvent A) and 5mM nonafluorovaleric acid in methanol (Solvent B) or 10 mM octanesulfonic acid in water (solvent A) and methanol (Solvent B), at room temperature and a 1 mL/minute flow rate. UV detection at 220 nm and ^{14}C by continuous mixing with liquid scintillator.	
3.4.10	Microbial biomass measurement	Yes Microbial biomass was determined at the start and end of the test by a modification of the respiratory method.	
3.4.11	Controls	No controls were used other than for physico-chemical parameters and microbial biomass.	
3.4.12	Statistics	DT_{50} and DT_{90} degradation kinetics were calculated with the MicroCal Origin v3.5 program. First order kinetics were applied.	

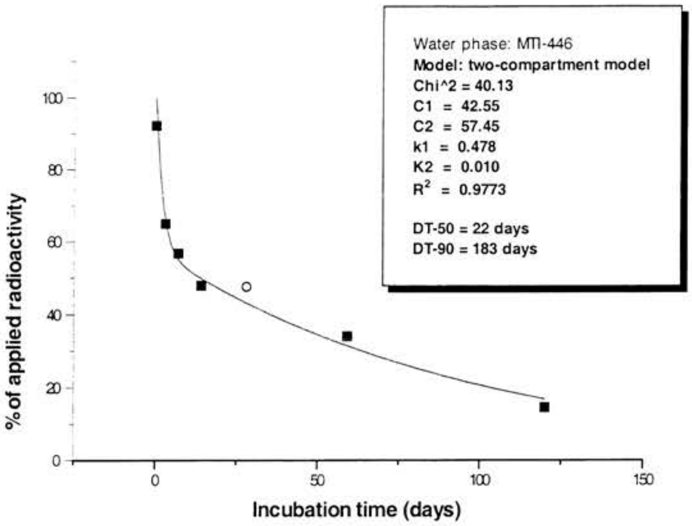
4 RESULTS

4.1 Degradation of test substance

4.1.1 Graph

Dinotefuran dissipation from water phase

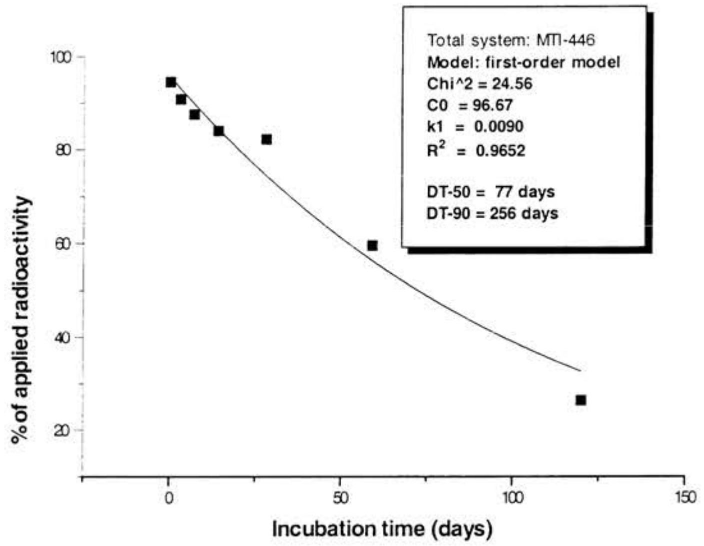
X



Section A7.2.1-2 Anaerobic degradation in soil, initial study

Annex Point VII 4, XII.1.1

Dinotefuran degradation from total system



X

4.1.2 Degradation

In the experiment, total recoveries of radioactivity (mass balances) were 96.0±2.5% of the applied radioactivity (AR). Radioactivity in the water phase decreased from a mean value of 94.6% on day 0 to 58.8% on day 7 and a mean value of 25.4% on day 120. There was a corresponding increase of the radioactivity in soil reaching a maximum of 62.6% AR at the end of the test. The majority of this fraction was extractable, amounting to 27.8% AR at day 3 and 53.5% at day 120. The non-extractable radioactivity reached a maximum of 10.7% on day 59. Organic matter fractionation indicated that the non-extractable radioactivity was mainly bound to the immobile humic acids and humic fraction. Volatile radioactivity was mostly associated with $^{14}CO_2$, representing a maximum of 4.2% AR (day 120). Only 0.1% AR could be attributed to organic volatiles.

DT_{50} values were calculated as follows:

	Anaerobic DT_{50} [days]	
	Water phase	Total system
DT_{50}	22	77
DT_{90}	183	256

X

A summary of the results is given in tabular form in Table A7.2.1.2-4.

4.1.3 Other observations

The microbial biomass and the physico-chemical parameters stayed relatively constant throughout the study. Anaerobic conditions were proven.

4.1.4 Degradation of TS in abiotic control

No abiotic control used

4.1.5 Degradation of reference substance

No reference substance used