Section A7.5.1.1 Inhibition to microbial activity (terrestrial)

Annex Point IIA7.4

3.3	**Testing procedure**	
3.3.1	Soil sample / inoculum / test organism	see Table A7.5.1.1-1
3.3.2	Test system	see Table A7.5.1.1-3
3.3.3	Application of TS	see Table A7.5.1.1-4
3.3.4	Test conditions	see Table A7.5.1.1-5
3.3.5	Test parameter	• Microbial biomass and optimum glucose amendment • pH values of the soils • Glucose induced short term respiration • Nitrification of lucerne meal • Ammonification • Nitrification
3.3.6	Analytical parameter	• evolved CO_2 • ammonium-nitrogen • nitrite-nitrogen • nitrate-nitrogen
3.3.7	Duration of the test	28 days
3.3.8	Sampling	0 – 3 hours, 14 days, 28 days after treatment
3.3.9	Monitoring of TS concentration	No
3.3.10	Controls	Unamended control, control and blank formulation treated soil
3.3.11	Statistics	• The Dixon-test as reported by Sachs (1984) or Dixon (1953) was used to eliminate outliers in the respiration and nitrification experiments. • In the respiration and nitrification experiments, the mean of individual values at the end of their respective incubation period were statistically evaluated by Dunett's t-test (two-tailed, 5%) to find significant differences between the control and treated samples. • For the calculation of the microbial biomass the initial and constant CO_2 production rate per 100 g of dry soil (V_{CO2}) and Anderson and Domsch (1978) equation were used.
		4 RESULTS
4.1	**Range finding test**	Not performed
4.1.1	Concentration	n.a.
4.1.2	Effect data	n.a.
4.2	**Results test substance**	

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4.2.1	Initial concentrations of test substance	Low dose:	300 g a.i./ha (corresponding to 2.0 mg MTI446 20 % SG/kg dry soil	X
		High dose:	3.0 kg a.i./ha (corresponding to 20 mg MTI-446 20% SG/kg dry soil)	
4.2.2	Actual concentrations of test substance	not performed		
4.2.3	Growth curves	n.a.		
4.2.4	Cell concentration data	n.a.		
4.2.5	Concentration/ response curve	n.a.		
4.2.6	Effect data	Give in tabular form individual and mean values for quantities of determined analytical parameter (e.g. CO_2-release) at each tested TS concentration; report calculated E_{50} value (including 95 % c.l.) and, if appropriate, EC_x (e.g. EC_{10}, EC_{100}), and NOEC values		
4.2.7	Other observed effects	Indicate e.g. any observed inhibition phenomena		
4.3	**Results of controls**	Include data for all controls applied: e.g. control without test substance; abiotic control; carrier control		
4.4	**Test with reference substance**	Performed		
4.4.1	Concentrations	Dinoseb acetetate was tested at 25 mg/kg dry soil		
4.4.2	Results	not reported		

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

Guidelines:

SETAC-Europe: Procedures for assessing the environmental fate and ecotoxicity of pesticides, March 1995

Under consideration of:

- Biologische Bundesanstalt für Land-und Forstwirtschaft (BBA), Deutschland. Richtlinien für die amtliche Prüfung von Pflanzenschutzmitteln Teil VI 1-1 (2.Auflage). Auswirkungen auf die Aktivität der Bodenmikroflora, März 1990
- Draft OPPTS 850.5100 Soil microbial community toxicity test; United States Environmental Protection Agencey (EPA), April 1996

No relevant deviations from test guidelines.

Method:

Soil samples of 150 g dry weight were set up for each soil in order to determine the short-term respiration and the nitrification process with time after the application.

After application, control as well as the test item, blank and dinoseb acetate treated samples were adjusted to 40 % of their maximum water holding capacity (i.e. 15.6 g water per 100 g dry soil). The samples were

Section A7.5.1.1 Inhibition to microbial activity (terrestrial)

Annex Point IIA7.4

incubated in the dark at 20 ± 2 °C.

Respiration as well as nitrification were determined for the intervals 0 – 3 hours, 14 and 28 days after treatment.

The pH of the soil was determined at each sampling interval.

The microbial biomass was determined according to Anderson and Domsch (1978). For short term respiration experiments, the glucose concentration which exerted a maximum respiration response was added.

The concentration of ammonium, nitrite and nitrate were determined for each sampling interval in a 2N KCl extract of the soil sample.

Determinations of the soil pH were performed with 10 g dry soil aliquots suspended in 25 mL 0.01 M $CaCl_2$.

The microbial biomass and the short-term respiration were determined by semi-continuously measurement of the evolved CO_2 by means of a infrared gas analyser.

The concentrations of ammonium-, nitrite- and nitrate-nitrogen were determined by analysing 2M KCl extracts of the soil samples, using a Flow Injection Analyser.

5.2 Results and discussion

The maximum rate of initial CO_2 evolution from 100 g dry soil equivalent was 0.295 mL/h for soil Speyer 2.3. The microbial biomass expressed as microbial carbon per 100 grams of dry weight soil was calculated to be 12.3 mg microbial carbon.

The pH value of 7.2 was measured for the control soil without lucerne meal at day 0. The corresponding pH with lucerne meal was 7.1. During incubation the pH ranged from 6.9 – 7.2 for the lucerne-free and lucerne-containing samples. Thus, no significant pH changes in lucerne-free soil and a slight increase in lucerne-containing soil took place during the incubation.

No significant influence of MTI-446 20 % SG on soil microbial respiration in soil Speyer 2.3 was observed.

According to Malkomes scheme, rates up to ten times the maximum field rate of MTI-446 20% SG in soil Speyer 2.3 results in neglible effects on soil respiration. Dinoseb acetate results in tolerable effects on soil respiration, but with time the effect on microorganisms is increasing.

For ammonification, there was no deviation between untreated and treated soil samples and values were constant at 0.02 mg per 100 g dry soil. The dinoseb acetate treated soil samples were significantly different from the controls on day 0 and 14, but identical on day 28.

For nitrification, the treatment with MTI-446 20 % SG had no influence on the nitrite formation and transformation.

Mean nitrate levels increased in all samples. The calculated deviation to the control showed only little effects after 28 days of incubation.

Results for the inorganic nitrogen level confirmed that MTI-446 20 % SG had no adverse effect on the nitrification. The soil treated with dinoseb acetate showed a high effect on total inorganic nitrogen.

In the Malkomes scheme the results for MTI-446 20 % SG range in the area of a neglible effect. The results for dinoseb acetate range after 28

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Annex Point IIA7.4

		days in the area of a tolerable effect.	
5.2.1	NOEC	4mg a.i./kg dry soil	X
5.2.2	EC_{10}	n.d.	
5.2.3	EC_{50}	>4mg a.i./kg dry soil	
5.3	**Conclusion**	MTI-446 20 % SG will not cause adverse effects on organic matter turnover, and hence on soil fertility, even at rates up to ten times the recommended filed rate i.e.4 mg a.i./kg dry soil (equivalent to 20 mg MTI-44620% SG/kg). The reference item dinoseb acetate had a significant effect on the microflora demonstrating the sensitivity of the test system and validity of the experimental design.	X
5.3.1	Reliability	1	
5.3.2	Deficiencies	No	

Table A7.5.1.1-1: Microbial sample / Inoculum

Criteria	Details
Nature	Soil sample Speyer 2.3
Sampling site:	Landwirtschaftliche Untersuchungs- und Forschungsanstalt (LUFA), Speyer, Germany
Geographical reference on the sampling site	not reported
Data on the history of the site	The soil has not been subject to any pesticide or organic fertilizer treatment for at least four years. The soil was treated with inorganic fertiliser in 1996 and 1998.
Use pattern	not reported
Depth of sampling [cm]	0 – 20 cm
Sand / Silt / Clay particle size [%]	Classification ISSS clay 8.1 silt 11.1 sand 80.8 Classification USDA clay 8.1 silt 26.1 sand 65.8 Classification DIN clay 8.1 silt 28.4 sand 63.5
pH ($CaCl_2$)	6.6 ± 0.3
Organic carbon content [% dry weight]	1.18
Nitrogen content [% dry weight]	2.58
Cation exchange capacity [meq/100 g soil]	11 ± 3
Initial microbial biomass	12.3
Reference of methods	not reported
Collection / storage of samples	not reported
Preparation of inoculum for exposure	n.a.
Pretreatment	n.a.

Table A7.5.1.1-2: Test organism (*if applicable*)

Criteria	Details
Species	n.a.
Strain	n.a.
Source	n.a.
Sampling site	n.a.
Laboratory culture	n.a.
Method of cultivation	n.a.
Preparation of inoculum for exposure	n.a.
Pretreatment	n.a.
Initial cell concentration	n.a.

Table A7.5.1.1-3: Test system

Criteria	Details
Culturing apparatus	not reported
Number of vessels / concentration	n.a.
Aeration device	n.a.
Measuring equipment	Infrared gas analyzer Flow Injection analyser
Test performed in closed vessels	not reported

Table A7.5.1.1-4: Application of test substance

Criteria	Details
Application procedure	The test item was applied in 1 mL purified water
Carrier	The reference item was applied using fortified quartz sand (1.5 g per 150 g soil sample)
Concentration of liquid carrier [% v/v]	n.a.
Liquid carrier control	n.a.
Other procedures	n.a.

Table A7.5.1.1-5: Test conditions

Criteria	Details
Organic substrate	lucerne meal
Incubation temperature	20 ± 2 °C
Soil moisture	40 % MWC
Method of soil incubation	not reported
Aeration	not reported

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	17 October 2012
Materials and Methods	Applicant's version considered acceptable, noting the following: 3.1.3 Test item contains 20% dinotefuran (nominal) 3.1.7 Solubility in water is not given in the report so cannot verify this figure.
Results and discussion	Applicant's version considered acceptable, noting the following: The figures given at 5.2.1/3 refer to the content of active ingredient, whereas the figures given in 4.2.1 refer to the amount of 20% formulation.
Conclusion	Applicant's version considered acceptable, noting the following: Should read '...recommended field rate...'
Reliability	1
Acceptability	Acceptable
Remarks	
	COMMENTS FROM ...
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

Section 7.5.1.2 Annex Point IIIA, XIII3.2	**Acute toxicity to earthworms or other soil non-target macro-organisms**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	**Official use only**
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [X]**	
Detailed justification:	Required for products used outside buildings as well as products to be used by gassing, fogging or fumigation, where release to soil is possible. Dinotefuran is intended for indoor use as a gel bait, therefore this test is not required.	
Undertaking of intended data submission [ ]	Not applicable	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	22 November 2012	
Evaluation of applicant's justification	The rapporteur agrees with the justification of non-submission given by the applicant.	
Conclusion		
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date		
Evaluation of applicant's justification		
Conclusion		
Remarks		

Section 7.5.1.3 **Annex Point IIIA, XIII3.2**	**Acute toxicity to plants**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [X]**	
Detailed justification:	Required for products used outside buildings as well as products to be used by gassing, fogging or fumigation, where release to soil is possible. Dinotefuran is intended for indoor use as a gel bait, therefore this test is not required.	
Undertaking of intended data submission [ ]	Not applicable	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	22 November 2012	
Evaluation of applicant's justification	Rapporteur agrees with justification for non-submission of data given by applicant.	
Conclusion		
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date		
Evaluation of applicant's justification		
Conclusion		
Remarks		

Section A7.5.2.1
Annex Point IIIA XIII 3.2

Effects on earthworm reproduction
Eisenia fetida

			Official use only
		1 REFERENCE	
1.1	**Reference**	Bätscher, R., 2001, Effects of MTI-446 on survival, growth and reproduction of the earthworm *Eisenia fetida,* RCC Ltd, unpublished report no. 731193, January 17, 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 ISO 11268-2: 1998(E) BBA Guideline Part VI, 2-2, 1994	
2.2	**GLP**	Yes	
2.3	**Deviations**	No	
		3 METHOD	
3.1	**Test material**	As given in section 2	X
3.1.1	Lot/Batch number	5500310	
3.1.2	Specification		
3.1.2.1	Purity	97.26 %	
3.1.2.2	Composition of Product	n.a.	
3.1.3	Further relevant properties	Solubility in water: 39.83 g/L at 20 °C Stability in water: > 24 hours (Sponsor information)	X
3.1.4	Method of analysis	No test item analysis was conducted	
3.2	**Reference substance**	Yes Carbendazim 2.5 mg/kg dry soil was tested as a positive control	
3.2.1	Method of analysis for reference substance	No reference item analysis was conducted	
3.3	**Testing procedure**		
3.3.1	Preparation of the test substance	see Table A7.5.2.1-1	
3.3.2	Application of the test substance	The test item was mixed into the soil as an aqueous dilution.	
3.3.3	Test organisms	see Table A7.5.2.1-2	
3.3.4	Test system	see Table A7.5.2.1-3	
3.3.5	Test conditions	see Table A7.5.2.1-4	X
3.3.6	Test duration	56 days	
3.3.7	Test parameter	Mortality, growth and reproduction	

Section A7.5.2.1
Annex Point IIIA XIII 3.2

Effects on earthworm reproduction
Eisenia fetida

3.3.8	Examination	Mortality and growth of the adults was determined 28 days after start of exposure. Reproduction was determined 56 days after start of exposure.
3.3.9	Monitoring of test substance concentration	No
3.3.10	Statistics	Mortality: The 28 day LC_{50} and its 95 % confidence intervals were calculated by Moving Average Interpolation Growth rate: For each test vessel, the difference of the mean body wet weight of the surviving organisms between the start and the end of exposure was calculated. The mean growth rates of the surviving worms in the test item treatment groups were compared to the negative control and were statistically evaluated by means of a multiple Williams-test after a one-way analysis of variance (ANOVA). The mean growth rate in the positive control was compared to the negative control value and was statistically evaluated by means of a Student t-test.
		4 RESULTS
4.1	**Filter paper test**	Not performed
4.1.1	Concentration	n.a.
4.1.2	Number/ percentage of animals showing adverse effects	n.a.
4.1.3	Nature of adverse effects	n.a.
4.2	**Soil test**	
4.2.1	Initial concentrations of test substance	0.08, 0.2, 0.5, 1.3, 3.2 and 8.0 mg/kg dry weight artificial soil
4.2.2	Effect data (Mortality)	After 28 days the mortality rate of adult organism in the negative control was 2.5 %. Mortality in the treatment groups 0.08, 0.2, 0.5, 1.3 and 3.2 mg/kg dry soil did not exceed 7.5 %. At the highest test concentration (8.0 mg/kg) the mortality rate was 92.5 %.
4.2.3	Effect data (growth of adult organism)	The growth rate of adult earthworms in the control was 43 % throughout the 28 day adult exposure period. The growth rates of adult earthworms in the 0.08 and 0.2 mg/kg treatment groups were 45 and 39 % throughout the 28-day adult exposure period respectively. The results of a Williams-test (one-sided, $\alpha = 0.05$) showed no statistically significant difference to the negative control. The growth rates of adult earthworms in the 0.5, 1.3 and 3.2 mg/kg treatment groups were 24, 17, and 14 % throughout the 28-day adult exposure period. The results of a Williams-test (one-sided, $\alpha = 0.05$) showed statistically significant difference when compared to the negative control. The growth rate of the three surviving earthworms in the 8.0 mg/kg treatment group was -31 % throughout the 28-day adult exposure period. The results of a Williams-test (one-sided, $\alpha = 0.05$) showed

statistically significant difference to the negative control

4.2.4 Effect data (reproduction)

The reproduction rate in the control was found to be 8.2 ± 2.2 (CV 27.5%) after the 28 day reproduction period.

The reproduction rates in the 0.08, 0.2 and 0.5 mg/kg treatment group were 8.5 ± 2.0 (CV 23.1), 7.6 ± 1.2 (CV 15.6) and 7.9 ± 1.5 (CV 18.7), respectively. The results of a Williams-test (one-sided, $\alpha = 0.05$) showed no statistically significant difference when compared to the negative control.

The reproduction rates in the 1.3 and 3.2 mg/kg treatment group were 2.9 ± 1.6 (53.9) and 1.4 ± 1.3 (CV 92.6), respectively. The results of a Williams-test (one-sided, $\alpha = 0.05$) showed statistically significant difference when compared to the negative control.

In the highest treatment group (8.0 mg/kg), reproduction was completely inhibited.

4.2.5 Other effects

Food consumption of adult earthworms was reduced in the higher treatment groups. Only visual inspections for food consumption were carried out, but a clear dose response in the reduction of food consumption was noticeable.

4.3 Results of controls

4.3.1 Mortality

Treatment group	Vessel No.	Number worms	Alive after 28 days	Sum dead after 28 days	Mortality after 28 days
control	1	10	10	1	2.5
	2	10	10		
	3	10	9		
	4	10	10		
positive control*	1	10	10	0	0
	2	10	10		
	3	10	10		
	4	10	10		

* Carbendazim 2.5 mg a.i./kg dry soil

4.3.2 Number/ percentage of earthworms showing adverse effects

none

4.3.3 Nature of adverse effects

none

4.4 Test with reference substance

Performed

4.4.1 Concentrations

Carbendazim 2.5 mg a.i./kg dry soil

4.4.2 Results

No mortality was observed after the adult exposure period of 28 days.

Section A7.5.2.1
Annex Point IIIA XIII 3.2

Effects on earthworm reproduction

Eisenia fetida

The growth rate of adult earthworms after 28 days of exposure was 40 % and was not statistically significant different compared to the negative control (Student-t-test, ones-sided smaller, $\alpha = 0.05$).

The mean reproduction rate of earthworms was 33% of control and found to be statistically significant different compared to the control (Student-t-test, one-side smaller, $\alpha = 0.05$).

The results of the reference item treatment showed sensitivity of the earthworms and satisfying test conditions.

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

Guidelines:

ISO 11268-2: 1998(E)

BBA Guideline Part VI, 2-2, 1994

No relevant deviations from test guidelines

Method:

A total number of 40 earthworms (four replicate of 10 each) were tested at the following dose rates:

- a negative control (water only),
- a positive control (2.5 mg carbendazim/kg dry soil)
- test item treatments at 0.08, 0.2, 0.5, 1.3, 3.2 and 8.0 mg/kg dry soil

The test item was mixed into the soil as aqueous solution. Artificial soil according to the test guidelines was used as a test substrate.

The study consisted of two phases:

- adult earthworms were exposed to the test item for 28 days
- after this period, the adults were removed from the test vessels and cocoons and juvenile earthworms remained in the treated soil for another 28 days

The test was carried out at a controlled temperature of 19 – 22 °C under a 16-hour light to 8-hour dark period (light intensity 640 – 750 Lux).

At preparation of the test substrate, air-dried horse manure was mixed into the substrate of each vessel as source of food. After addition of the earthworms, horse manure was additionally distributed evenly over the soil surface of each vessel. During the first 28 days of the study, the worms were fed once a week with a suitable amount of food.

After 28 days, all vessels were emptied and the number of live earthworms determined. The 28-day LC_{50} and its 95 % confidence interval were calculated by Moving Average Interpolation.

The growth rate as the difference in body wet-weight between start of exposure and end of adult exposure phase was determined for each test vessel. The mean growth rates of surviving earthworms in the test item treatments were compared to the control and were statistically evaluated by means of a multiple Williams-test after a one-way analysis of variance (ANOVA). The mean growth rate of the positive control was compared to the control and was statistically evaluated by means of a Student-t-test.

The reproduction rate as the number of surviving juveniles was determined after another 28 days exposure for each test vessel. The mean reproduction rates of the test item treatment groups were compared to the control by means of a multiple Williams-test after a

		one-way analysis of variance (ANOVA). The 28-day EC_{50} on inhibition of the reproduction rate and its 95% confidence interval were calculated by Probit Analysis. The mean reproduction rate of the positive control was compared to the negative control and statistically evaluated by means of a Student-t-test.
5.2	**Results and discussion**	After 28 days, the mortality rate of adult organism in the negative control was 2.5 %. Mortality in the treatment groups 0.08, 0.2, 0.5, 1.3 and 3.2 mg/kg dry soil did not exceed 7.5 %. At the highest test concentration (8.0 mg/kg) the mortality rate was 92.5 % The growth rate of adult earthworms in the control was 43 % throughout the 28-day adult exposure period. The growth rates of adult earthworms in the 0.08 and 0.2 mg/kg treatment groups were 45 and 39 % throughout the 28-day adult exposure period respectively. The results of a Williams-test (one-sided, $\alpha = 0.05$) showed no statistically significant difference when compared to the negative control. The growth rates of adult earthworms in the 0.5, 1.3 and 3.2 mg/kg treatment groups were 24, 17, and 14 %throughout the 28-day adult exposure period. The results of a Williams-test (one-sided, $\alpha = 0.05$) showed statistically significant difference to the negative control. The growth rate of the three surviving earthworms in the 8.0 mg/kg treatment group was -31 % throughout the 28-day adult exposure period. The results of a Williams-test (one-sided, $\alpha = 0.05$) showed statistically significant difference to the negative control The reproduction rate in the control was found to be 8.2 ± 2.2 (CV 27.5%) after the 28 day reproduction period. The reproduction rates in the 0.08, 0.2 and 0.5 mg/kg treatment group were 8.5 ± 2.0 (CV 23.1), 7.6 ± 1.2 (CV 15.6) and 7.9 ± 1.5 (CV 18.7), respectively. The results of a Williams-test (one-sided, $\alpha = 0.05$) showed no statistically significant difference to the negative control. The reproduction rates in the 1.3 and 3.2 mg/kg treatment group were 2.9 ± 1.6 (CV 53.9) and 1.4 ± 1.3 (CV 92.6), respectively. The results of a Williams-test (one-sided, $\alpha = 0.05$) showed statistically significant difference to the negative control. In the highest treatment group (8.0 mg/kg), reproduction was completely inhibited. Food consumption of adult earthworms was reduced in the higher treatment groups. Only visual inspections for food consumption were carried out, but a clear dose response in the reduction of food consumption was noticeable.
5.2.1	LC_{50}	The 28-day LC_{50} for adult mortality was determined to 5.1 mg/kg dry soil weight with 95 % confidence intervals ranging from 4.1 to 6.2 mg/kg.
5.2.2	EC_{50}	The EC_{50} for living offspring after 28 days of exposure, reproduced by adults within 28 days of exposure was determined to be 1.2 mg/kg dry soil with confidence intervals ranging from 0.6 to 2.3 mg/kg.
5.2.3	NOEC/LOEC	The overall NOEC was determined to be 0.2 mg/kg dry soil and the overall LOEC was determined to be 0.5 mg/kg dry soil.
5.3	**Conclusion**	The mortality of adult earthworm in the control was within the recommended range according the guidelines. The positive control

Section A7.5.2.1 **Effects on earthworm reproduction**
Annex Point IIIA XIII 3.2 ***Eisenia fetida***

		carbendazim demonstrated the sensitivity of the test system and satisfying test conditions. A clear dose response for mortality, growth and reproduction was demonstrated.
5.3.1	Other Conclusions	none
5.3.2	Reliability	1
5.3.3	Deficiencies	No

Table A7.5.2.1-1: Preparation of TS solution

Criteria	**Details**
Type and source of dilution water	purified water
Alkalinity / Salinity	not reported
Hardness	not reported
pH	not reported
Oxygen content	not reported
Conductance	not reported
Holding water different from dilution water	not reported
In case of the use of an organic solvent	
Dispersion	n.a.
Vehicle	n.a.
Concentration of vehicle	n.a.
Vehicle control performed	n.a.
Other procedures	n.a.

Table A7.5.2.1-2: Test organisms

Criteria	**Details**
Species/strain	*Eisenia fetida*
Source of the initial stock	Blades Biological, Kent/London, TN8 7DX, UK
Culturing techniques	Not reported
Age/weight	age: 7 – 8 months weight: 300 – 600 mg
Pre-treatment	Earthworms were acclimated for three days to the artificial soil and test temperature

Table A7.5.2.1-3: Test system

Criteria	Details
Artificial soil test substrate	Sphagnum peat: 10 % Kaolinite clay: 20 % Sand: 69 % $CaCO_3$: 0.3 % Food: 1 %
Test mixture	The following nominal concentrations were tested: 0.08, 0.2, 0.5, 1.3, 3.2 and 8.0 mg/kg dry soil. A positive control with the reference item Derosal® (active ingredient 60 % Carbendazim) was tested at 4.2 mg/kg dry soil (corresponding to 2.5 mg carbendazim a.i./kg dry soil)
Size, volume and material of test container	Glass dish, 14 cm diameter, 7 cm high
Amount of artificial soil (kg)/ container	527 g (corresponding to 500 g dry weight)
Nominal levels of test concentrations	0.08, 0.2, 0.5, 1.3, 3.2 and 8.0 mg MTI-446/kg dry soil
Number of replicates/concentration	4
Number of earthworms/test concentration	40
Number of earthworms/container	10
Light source	Not reported
Test performed in closed vessels due to significant volatility of test substrate	No

Table A7.5.2.1-4: Test conditions

Criteria	Details
Test temperature	19 – 22 °C
Moisture content and pH	<table><tr><th>Test concentration [mg/kg]</th><th>Water content after 8 weeks* [%]</th><th>pH after 8 weeks*</th></tr><tr><td>control</td><td>36</td><td>5.9</td></tr><tr><td>0.08</td><td>35</td><td>6.0</td></tr><tr><td>0.2</td><td>37</td><td>6.1</td></tr><tr><td>0.5</td><td>34</td><td>5.9</td></tr><tr><td>1.3</td><td>37</td><td>5.9</td></tr><tr><td>3.2</td><td>37</td><td>5.9</td></tr><tr><td>8.0</td><td>35</td><td>5.9</td></tr><tr><td>positive control</td><td>36</td><td>6.0</td></tr></table> initial water content: 33 % initial pH: 6.2
Adjustment of pH	No
Light intensity / photoperiod	640 - 750 Lux, 16 hours light and 8 hours dark
Relevant degradation products	none

Table A7.5.2.1-5: Mortality data: Number of living adult earthworms and % mortality after 28 days of exposure

Test concentration [mg/kg][1]	Vessel No.	Number of worms	Number of alive worms after 28 days	Sum of dead after 28 days	Mortality after 28 days (%)
control	1	10	10	1	2.5
	2	10	10		
	3	10	9		
	4	10	10		
0.08	1	10	10	0	0
	2	10	10		
	3	10	10		
	4	10	10		
0.2	1	10	10	0	0
	2	10	10		
	3	10	10		
	4	10	10		
0.5	1	10	10	0	0
	2	10	10		
	3	10	10		
	4	10	10		
1.3	1	10	10	1	2.5
	2	10	9		
	3	10	10		
	4	10	10		
3.2	1	10	8	3	7.5
	2	10	10		
	3	10	9		
	4	10	10		
8.0	1	10	0	37	92.5
	2	10	0		
	3	10	3		
	4	10	0		
positive control*	1	10	10	0	0
	2	10	10		
	3	10	10		
	4	10	10		

* *Carbendazim 2.5 mg a.i./kg dry soil*

[1] nominal

Table A7.5.2.1-6: Mean body wet weights of adult earthworms at the test start and after 28 days of exposure

Test concentration	Mean body weight at test start	Mean body weight after 28 days	Mean change		
[mg/kg]	[mg]*	[mg]*	[mg]*	[%]	STAT#
control	424 (23)	605 (71)	181 (78)	43	-
0.08	429 (30)	623 (53)	194 (30)	45	n.s.
0.2	443 (42)	613 (38)	170 (24)	39	n.s.
0.5	419 (27)	519 (45)	100 (25)	24	s.
1.3	441 (26)	516 (46)	75 (34)	17	s.
3.2	447 (16)	511 (38)	64 (36)	14	s.
8.0	421 (19)	270**	- 124**	- 31	s.
positive control	424 (21)	596 (51)	172 (35)	40	n.s.

* mean over all four replicates (Standard Deviation)

** surviving earthworm only in one replicate, no SD calculated

Statistical comparison of the changes in mean body weight of the treatments compared with the control

n.s. not statistically significant

s. statistically significant

Table A7.5.2.1-7: Reproduction of earthworms

Test concentration	Juveniles	Reproduction rate (per surviving adult)			STAT#
[mg/kg]	Mean ± SD	Mean ± SD	CV (%)	% of control	
control	80 ± 22	8.2 ± 2.2	27.5	100	-
0.08	85 ± 20	8.5 ± 2.0	23.1	104	n.s.
0.2	76 ± 12	7.6 ± 1.2	15.6	93	n.s.
0.5	79 ± 15	7.9 ± 1.5	18.7	96	n.s.
1.3	28 ± 15	2.9 ± 1.6	53.9	36	s.
3.2	13 ± 12	1.4 ± 1.3	92.6	17	s.
8.0	0 ± 0	0 ± 0	-	0	s.
positive control	27 ± 18	2.7 ± 1.8	67.1	33	s.

Statistical comparison of the changes in mean body weight of the treatments compared with the control

n.s. not statistically significant

s. statistically significant

Table A7.5.2.1-8 Effect data

Endpoint	mg/kg dry soil[1]
LC_{50} adult mortality	5.1 (4.1 – 6.2)
EC_{50} reproduction	1.2 (0.6 – 2.3)
NOEC overall	0.2
LOEC overall	0.5

[1] based on nominal concentrations

Table A7.5.2.1-9: Validity criteria for acute earthworm test according to OECD 207

	Fulfilled	Not fulfilled
Mortality of control animals < 10%	X	

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	9 October 2012
Materials and Methods	Applicant's version considered acceptable, noting the following: 3.1 Test material is MTI-446 (dinotefuran) as given in section 2 of the report. 3.1.3 Further relevant properties Solubility in water: 54.3 g/l at 20°C 3.3.5 Test conditions Table A7.5.2.1-4 '*' required in key for moisture content and pH
Results and discussion	Applicant's version considered acceptable
Conclusion	Applicant's version considered acceptable
Reliability	1
Acceptability	Acceptable
Remarks	
	COMMENTS FROM ... *(specify)*
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

Section 7.5.2.2 Annex Point IIIA, XIII3.2	**Long-term test with terrestrial plants**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	**Official use only**
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [X]**	
Detailed justification:	This study is required when the intended use of dinotefuran results in direct release to the terrestrial compartment and presents a risk terrestrial plants. Dinotefuran is intended for indoor use, therefore this test is not required.	
Undertaking of intended data submission [ ]	Not applicable	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	22 November 2012	
Evaluation of applicant's justification	The rapporteur agrees with the justification of non-submission given by the applicant.	
Conclusion		
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date		
Evaluation of applicant's justification		
Conclusion		
Remarks		

Section 7.5.3.1.1 **Annex Point IIIA, XIII.1.1**	**Effects on birds** **Acute oral toxicity**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [X]**	
Detailed justification:	This study is required when the intended use of dinotefuran results in direct release to the terrestrial compartment. Dinotefuran is intended for indoor use, therefore this test is not required.	
Undertaking of intended data submission [ ]	Not applicable	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	22 November 2012	
Evaluation of applicant's justification	The rapporteur agrees with the justification of non-submission given by the applicant.	
Conclusion		
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date		
Evaluation of applicant's justification		
Conclusion		
Remarks		

Section 7.5.3.1.2 **Annex Point IIIA, XIII.1.2**	**Effects on birds** **Short-term toxicity**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	**Official use only**
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [X]**	
Detailed justification:	This study is required when the intended use of dinotefuran results in direct release to the terrestrial compartment. Dinotefuran is intended for indoor use, therefore this test is not required.	
Undertaking of intended data submission [ ]	Not applicable	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	22 November 2012	
Evaluation of applicant's justification	The rapporteur agrees with the justification of non-submission given by the applicant.	
Conclusion		
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date		
Evaluation of applicant's justification		
Conclusion		
Remarks		

Section 7.5.3.1.3 **Annex Point IIIA, XIII.1.3**	**Effects on birds** **Effects on reproduction**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	**Official use only**
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [X]**	
Detailed justification:	This study is required when the intended use of dinotefuran results in direct release to the terrestrial compartment. Dinotefuran is intended for indoor use, therefore this test is not required.	
Undertaking of intended data submission [ ]	Not applicable	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	22 November 2012	
Evaluation of applicant's justification	The rapporteur agrees with the justification of non-submission given by the applicant.	
Conclusion		
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date		
Evaluation of applicant's justification		
Conclusion		
Remarks		

Section 7.5.4.1 Annex Point IIIA, XIII.3.1	**Acute toxicity to honeybees and other beneficial arthropods, for example predators**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	**Official use only**
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [X]**	
Detailed justification:	At least one test on bees and one on another beneficial arthropod may be generally required for insecticides, acaricides and substances in products to control other arthropods which are used outdoors. Dinotefuran is intended for indoor use, therefore this test is not required.	
Undertaking of intended data submission [ ]	Not applicable	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	22 November 2012	
Evaluation of applicant's justification	The rapporteur agrees with the justification of non-submission given by the applicant.	
Conclusion		
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date		
Evaluation of applicant's justification		
Conclusion		
Remarks		

Section 7.5.5.1 Annex Point IIA, VII.7.5	**Bioconcentration, further studies**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	**Official use only**
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [X]**	
Detailed justification:	Bioconcentration, further studies are required when the intended use of dinotefuran results in direct release to the terrestrial compartment. Dinotefuran is intended for indoor use, therefore this test is not required.	
Undertaking of intended data submission [ ]	Not applicable	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	22 November 2012	
Evaluation of applicant's justification	The rapporteur agrees with the justification of non-submission given by the applicant. In addition the log Kow of dinotefuran is -0.549 and consequently has little potential to bioaccumulate.	
Conclusion		
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date		
Evaluation of applicant's justification		
Conclusion		
Remarks		

Section 7.5.5 Annex Point IIA, VII.7.5	**Bioconcentration, terrestrial**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	**Official use only**
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [X]**	
Detailed justification:	When released to soil the intrinsic bio-concentration potential needs to be estimated based on, at least, the physical-chemical properties. Dinotefuran is intended for indoor use, therefore this test is not required.	
Undertaking of intended data submission [ ]	Not applicable	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	22 November 2012	
Evaluation of applicant's justification	The rapporteur agrees with the justification of non-submission given by the applicant.	
Conclusion		
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date		
Evaluation of applicant's justification		
Conclusion		
Remarks		

Section 7.5.6 Annex Point IIIA, XIII.3	**Effects on other terrestrial non-target organisms**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	**Official use only**
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [X]**	
Detailed justification:	Further tests (e.g. field tests) may be required if the risk assessment based on long-term terrestrial tests show that there is still a concern for the terrestrial compartment Long-term exposure to the terrestrial compartment is not likely as dinotefuran is intended for indoor use, therefore this test is not required.	
Undertaking of intended data submission [ ]	Not applicable	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	22 November 2012	
Evaluation of applicant's justification	The rapporteur agrees with the justification of non-submission given by the applicant.	
Conclusion		
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date		
Evaluation of applicant's justification		
Conclusion		
Remarks		

Section 7.5.7.1.1 **Annex Point IIIA, XIII.3.4**	**Effects on mammals** **Acute oral toxicity**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	**Official use only**
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [X]**	
Detailed justification:	For some product types, direct and/or indirect exposure for mammals is possible and some tests with mammals may be required in rare cases on the basis of concern for severe risk for the terrestrial environment. The intended use of dinotefuran will not result in direct and/or indirect release to the terrestrial environment and does not raise concern for severe risk for mammals or the terrestrial environment, therefore additional acute oral toxicity tests in mammals are not required. See Section A6.1.1 for acute oral toxicity studies in mammals.	
Undertaking of intended data submission [ ]	Not applicable	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	22 November 2012	
Evaluation of applicant's justification	The rapporteur agrees with the justification of non-submission given by the applicant.	
Conclusion		
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date		
Evaluation of applicant's justification		
Conclusion		
Remarks		

Section 7.5.7.1.2 **Annex Point IIIA, XIII.3.4**	**Effects on mammals** **Short-term toxicity**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	**Official use only**
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [X]**	
Detailed justification:	For some product types, direct and/or indirect exposure for mammals is possible and some tests with mammals may be required in rare cases on the basis of concern for severe risk for the terrestrial environment. The intended use of dinotefuran will not result in direct and/or indirect release to the terrestrial environment and does not raise concern for severe risk for mammals or the terrestrial environment, therefore additional acute oral toxicity tests in mammals are not required. See Section A6.3 for short-term toxicity studies in mammals.	
Undertaking of intended data submission [ ]	Not applicable	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	22 November 2012	
Evaluation of applicant's justification	The rapporteur agrees with the justification of non-submission given by the applicant.	
Conclusion		
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date		
Evaluation of applicant's justification		
Conclusion		
Remarks		

Section 7.5.7.1.3 **Annex Point IIIA, XIII.3.4**	**Effects on mammals** **Effects on reproduction**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	**Official use only**
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [X]**	
Detailed justification:	For some product types, direct and/or indirect exposure for mammals is possible and some tests with mammals may be required in rare cases on the basis of concern for severe risk for the terrestrial environment. The intended use of dinotefuran will not result in direct and/or indirect release to the terrestrial environment and does not raise concern for severe risk for mammals or the terrestrial environment, therefore additional acute oral toxicity tests in mammals are not required. See Section A6.5 for chronic toxicity studies in mammals and Section A6.8 for reproductive toxicity studies (including two generation reproduction studies).	
Undertaking of intended data submission [ ]	Not applicable	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	22 November 2012	
Evaluation of applicant's justification	The rapporteur agrees with the justification of non-submission given by the applicant.	
Conclusion		
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date		
Evaluation of applicant's justification		
Conclusion		
Remarks		

Section 7.5.7.1 Annex Point IIIA, XIII.3.4	**For some product types, direct and/or indirect exposure for mammals is possible and some tests with mammals may be required in rare cases on the basis of concern for severe risk for the terrestrial environment**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [X]**	
Detailed justification:	The intended use of dinotefuran will not result in direct and/or indirect release to the terrestrial environment and does not raise concern for severe risk for mammals or the terrestrial environment, therefore additional tests in mammals are not required. See Section A6.1 toxicity studies in mammals.	
Undertaking of intended data submission [ ]	Not applicable	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	22 November 2012	
Evaluation of applicant's justification	The rapporteur agrees with the justification of non-submission given by the applicant.	
Conclusion		
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date		
Evaluation of applicant's justification		
Conclusion		
Remarks		

Section A8 Subsection (Annex Point)	Measures necessary to protect man, animals and the environment	Official use only
8.1	**Recommended methods and precautions concerning handling, use, storage, transport or fire (IIA8.1)**	
8.1.0 Methods and precautions concerning placing on the market	Dinotefuran is produced outside of the EU; therefore this information is not required.	
8.1.1 Methods and precautions concerning production, handling and use of the active substance and its formulations	Recommendations: • Engineering controls: provide general ventilation. Use closed system or local exhaust ventilation. Provide safety shower and eye wash station near work area. • Hygiene measures: no information provided • Personal protective equipment: protective gloves, chemical cartridge respirator with an organic vapour cartridge, breathing apparatus that is an approved/certified respirator or equivalent, safety glasses or goggles, safety helmet, protective clothing, safety boots, apron. • The protection of bystanders: warn and evacuate people in the neighbourhood as necessary. • Precautionary measures against environmental exposure: stop leak if possible without personal risk. Vacuum or scoop up material and place in a disposal container.	
8.1.2 Methods and precautions concerning storage of the active substance and its formulations	Storage conditions: protect from direct sunlight. Keep away from heat, flame and all sources of ignition. Keep container tightly closed. Store in a segregated and approved area. Packaging material: plastics (solvent-resistant, e.g. polyethylene)	
8.1.3 Methods and precautions concerning transport of the active substance and its formulations	UN class: 9 (DOT, ADR/RID, IMDG and IATA) UN number: 3077 Special precautions for transport of the formulation: make sure that the containers have no puncture or leakage. Avoid rough handling of dropping. Prevent collapse of cargo piles. Protect from direct sunlight.	
8.1.4 Methods and precautions concerning fire of the active substance and its formulations	Extinguishing media: water jet, water fog, dry chemical, foam, CO_2. General hazard: no unusual fire or explosion hazard for normal industrial or commercial handling. Exposure of the active substance to heat may promote violent decomposition. Fire-fighting instructions: keep unnecessary and unprotected personnel away. Shut off supply if possible. Remove containers to safe place if possible. Keep containers and surroundings cool by spraying with water. Fight fire from an upwind position. Fire-fighting equipment: respiratory and eye protection required for fire-fighting personnel. Full protective equipment and self-contained breathing apparatus should be used for all indoor fires and any significant outdoor fires. Hazardous combustion products: carbon oxides, nitrogen oxides.	
8.2	**In case of fire, nature of reaction products, combustion gases, etc.**	

Section A8 Subsection (Annex Point)		Measures necessary to protect man, animals and the environment	Official use only
		(IIA8.2)	
8.2.1		The active substance is classified as not highly flammable.	
8.3		**Emergency measures in case of an accident (IIA8.3)**	
8.3.1	**Specific treatment in case of an accident, e.g. first-aid measures, antidotes, medical treatment if available**	Inhalation: remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Keep the affected person warm and at rest. Get medical attention immediately. Eye contact: immediately flush with plenty of water. Part eyelids with fingers to assure complete flushing. Check for and remove contact lenses if easily possible. Get medical attention if irritation persists. Skin contact: immediately remove contaminated clothing and shoes. Flush skin with large amounts of water, clean off with soap and water. Get medical attention if symptoms develop. Ingestion: do not induce vomiting. Get medical attention immediately. Rinse mouth with water if possible. Never give anything by mouth to an unconscious person.	
8.3.2	**Emergency measures to protect the environment**	Personal precautions: evacuate immediate area. Warn personnel of fire, explosion and health hazard. Remove all sources of ignition. Wear appropriate personal protective equipment as specified in point 8.1.1 above. Stop leak if possible without personal risk. Keep upwind, evacuate people downwind of spill. Environmental precautions: warn and evacuate people in the neighbourhood as necessary. Do not let this chemical enter the environment. Clean-up methods: vacuum or scoop up material and place in a disposal container.	
8.4		**Possibility of destruction or decontamination following release in or on the following: (a) Air; (b) Water, including drinking water; (c) Soil (IIA8.4)**	
8.4.1	**Possibility of destruction or decontamination following release in the air**	The active substance has a very low vapour pressure and so release into the air is very unlikely. There is no possibility of destruction or decontamination following release in the air.	
8.4.2	**Possibility of destruction or decontamination following release in water, including drinking water**	Do not allow entry into the environment. Vacuum or scoop up material and place in a disposal container. There is no possibility of destruction or decontamination following release in water.	
8.4.3	**Possibility of destruction or decontamination following release in or on soil**	Do not allow entry into the environment. Vacuum or scoop up material and place in a disposal container.	
8.5		**Procedures for waste management of the active substance for industry or professional users e.g. possibility of re-use or recycling, neutralisation, conditions for controlled discharge, and incineration (IIA8.5)**	

Section A8 Subsection (Annex Point)	Measures necessary to protect man, animals and the environment	
		Official use only
8.5.1 Possibility of re-use or recycling	The active substance cannot be recycled or re-used.	
8.5.2 Possibility of neutralisation of effects	The active substance cannot be neutralised.	
8.5.3 Conditions for controlled discharge including leachate qualities on disposal	Whatever cannot be saved for recovery may be burned in an approved incinerator or disposed in approved waste facility. Empty the container completely before disposal.	
8.5.4 Conditions for controlled incineration	Ensure compliance with local, state, federal and national regulations.	
8.6	**Observations on undesirable or unintended side-effects, e.g. on beneficial and other non-target organisms (IIA8.6)** Dinotefuran is intended for indoor use, therefore undesireable or unintended side-effects on beneficial and other non-target organisms is unlikely.	
8.7	**Identification of any substances falling within the scope of List I or List II of the Annex to Directive 80/68/EEC on the protection of groundwater against pollution caused by certain dangerous substances (IIA8.7*)*** No substances fall within the scope of List I or List II of the Annex to Directive 80/68/EEC on the protection of groundwater against pollution caused by certain dangerous substances.	

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	09/05/2013
Evaluation of Applicant's justification	The recommended methods and precautions concerning handling, use, storage, transport or fire appear comprehensive and acceptable.
Conclusion	The applicant's justification is acceptable.
Remarks	None.
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	*Discuss if deviating from view of rapporteur member state*

Section A9 Annex Point IIA - IX — Classification, Packaging and Labelling of the Active Ingredient according to Council Directive 67/548/EEC

Official use only

Hazard symbols	N	
Indication of danger	**Dangerous for the environment, harmful**	
Labelling symbol		
Risk phrases	**R50/53**	Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
	R57	Toxic to bees
Safety phrases	None	
Justification	N	Substances and preparations which, were they to enter into the environment, would present or might present an immediate or delayed danger for one or more components of the environment.
	R50/53	Based on the effects to aquatic organisms. The substance is chronically harmful to *Chironomus riparius* ($EC_{50} \leq 1$ mg/L).
	R57	Based on the effects to bees

Proposed classification according to Regulation EC 1272/2008

Classification and Labelling			Justification
GHS Pictograms			Ecotoxicological classification: Based on the effects to aquatic organisms. The substance is chronically harmful to *Chironomus riparius* ($EC_{50} \leq 1$ mg/L).
Signal words		Warning	
Classification		Acute 1 – Aquatic acute (Acute M-factor: 10) Chronic 1 – Aquatic chronic (Chronic M-factor: 10)	
Hazard statements		H400: Very toxic to aquatic life H410: Very toxic to aquatic life with long lasting effects	
Precautionary Statements	**General**	-	
	Prevention	P273: Avoid release to the environment	
	Response	P391: Collect spillage	
	Storage	-	
	Disposal	P501: Dispose of contents / container to …	

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	09/05/2013
Materials and Methods	Not applicable
Results and discussion	Not applicable

Conclusion	Not applicable
Reliability	Not applicable
Acceptability	Acceptable
Remarks	See Doc IIA, Section 1.5 for full Classification and Labelling information.
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	