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Section A7.5.1.2/02 and A7.5.2.1/02
Annex Point IIIA XIII.3.2

Acute toxicity to earthworms or other soil non-target macro-organisms
Reproduction study with earthworms or other soil non-target macro-organisms

Official use only

		1 REFERENCE
1.1	**Reference**	[redacted] (2000): [redacted]
1.2	**Data protection**	Yes
1.2.1	Data owner	[redacted]
1.2.2	Companies with letter of access	[redacted]
1.2.3	Criteria for data protection	[redacted]
		2 GUIDELINES AND QUALITY ASSURANCE
2.1	**Guideline study**	Yes ISO/FDIS 11267 (1998)
2.2	**GLP**	Yes
2.3	**Deviations**	No
		3 METHOD
3.1	**Test material**	[redacted]
3.1.1	Lot/Batch number	[redacted]
3.1.2	Specification	Purified active substance (PAI)
3.1.3	Purity	100%
3.1.4	Composition of Product	Not relevant, active substance tested
3.1.5	Further relevant properties	[redacted]
3.1.6	Method of analysis	[redacted]
3.2	**Reference substance**	[redacted]
3.2.1	Method of analysis for reference substance	[redacted]
3.3	**Testing procedure**	
3.3.1	Preparation of the test substance	[redacted]
3.3.2	Application of the test substance	[redacted]

Section A7.5.1.2/02 and A7.5.2.1/02
Annex Point IIIA XIII.3.2

Acute toxicity to earthworms or other soil non-target macro-organisms
Reproduction study with earthworms or other soil non-target macro-organisms

3.3.3	Test organisms	[redacted]
3.3.4	Test system	[redacted]
3.3.5	Test conditions	[redacted]
3.3.6	Test duration	[redacted]
3.3.7	Test parameter	[redacted]
3.3.8	Examination	[redacted]
3.3.9	Monitoring of test substance concentration	[redacted]
3.3.10	Statistics	[redacted]

4 RESULTS

4.1	**Filter paper test**	[redacted]
4.2	**Soil test**	
4.2.1	Initial concentrations of test substance	[redacted]
4.2.2	Effect data (Mortality)	[redacted]
4.2.3	Concentration / effect curve	[redacted]
4.2.4	Other effects	[redacted]
4.3	**Results of controls**	
4.3.1	Mortality	[redacted]
4.3.2	Reproduction	[redacted]
4.4	**Test with reference substance**	[redacted]
4.4.1	Concentrations	[redacted]
4.4.2	Results	[redacted]

Section A7.5.1.2/02 and A7.5.2.1/02
Annex Point IIIA XIII.3.2

Acute toxicity to earthworms or other soil non-target macro-organisms
Reproduction study with earthworms or other soil non-target macro-organisms

[redacted]

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	The toxicity of TI-435 to collembola was tested according to ISO/FDIS 11267 (1998). *Folsomia candida* were exposed to nominal concentrations of 0.01, 0.032, 0.1, 0.32 and 1.0 mg/kg dw artificial soil and effects on mortality and reproduction were observed.
5.2	**Results and discussion**	[redacted]
5.2.1	LC_{50} (mortality)	1.02 mg/kg dw soil (calculated)
5.2.2	LOEC (mortality)	1.0 mg/kg dw soil (nominal)
5.2.3	NOEC (mortality)	0.32 mg/kg dw soil (nominal)
5.2.4	[redacted] EC_{50} (reproduction)	0.76 mg/kg dw soil (calculated)
5.2.5	LOEC (reproduction)	1.0 mg/kg dw soil (nominal)
5.2.6	NOEC (reproduction)	0.32 mg/kg dw soil (nominal)
5.3	**Conclusion**	Validity criteria can be considered as fulfilled (see validity criteria summarised in Table A7_5_1_2_02-6).
5.3.1	Other Conclusions	
5.3.2	Reliability	1
5.3.3	Deficiencies	No

X

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
	COMMENTS FROM ... *(specify)*
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	

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Section 7.5.1.3/01 and 7.5.2.2/01
Annex Point IIIA XIII.3.4

Acute toxicity to plants
Long-term test with terrestrial plants

Official use only

1 REFERENCE

1.1	**Reference**	[redacted]. (2000a): [redacted]
1.2	**Data protection**	Yes
1.2.1	Data owner	[redacted]
1.2.2	Companies with letter of access	[redacted]
1.2.3	Criteria for data protection	[redacted]

2 GUIDELINES AND QUALITY ASSURANCE

2.1	**Guideline study**	Yes US EPA OPPTS 850.4100 and 850.4225
2.2	**GLP**	Yes
2.3	**Deviations**	No

3 METHOD

3.1	**Test material**	[redacted]
3.1.1	Lot/Batch number	[redacted]
3.1.2	Specification	[redacted]
3.1.3	Purity	[redacted]
3.1.4	Composition of Product	[redacted]
3.1.5	Further relevant properties	None
3.1.6	Method of analysis	[redacted]
3.2	**Preparation of TS solution for poorly soluble or volatile test substances**	[redacted]
3.3	**Reference substance**	[redacted]
3.4	**Blank formulation**	[redacted]
3.5	**Testing procedure**	
3.5.1	Preparation of spray mixtures	[redacted]

Section 7.5.1.3/01 and 7.5.2.2/01
Annex Point IIIA XIII.3.4

Acute toxicity to plants
Long-term test with terrestrial plants

[redacted]

3.5.2	Test plants	See Table A7_5_1_3_01-1
3.5.3	Test system	See Table A7_5_1_3_01-2
3.5.4	Test conditions	[redacted]
3.5.5	Test duration	15 days
3.5.6	Test parameter	[redacted]
3.5.7	Sampling	[redacted]
3.5.8	Method of analysis of the plant material	[redacted]
3.5.9	Statistics	[redacted]

4 RESULTS

4.1 Results test substance

4.1.1	Applied initial concentration	[redacted]
4.1.2	Phytotoxicity rating	[redacted]
4.1.3	Plant height	[redacted]
4.1.4	Plant dry weights	[redacted]
4.1.5	Emergence	[redacted]
4.1.6	Number of dead	[redacted]

	plants		
4.1.7	Effect data	[redacted]	
4.1.8	Concentration / response curve	[redacted]	
4.1.9	Other effects	[redacted]	
4.2	**Results of controls**		
4.2.1	Applied initial concentration	[redacted]	
4.2.2	Number/ percentage of plants showing adverse effects	[redacted]	
4.3	**Test with reference substance**	[redacted]	
		5 APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	Toxic effects of TI-435 50% WDG on seedling emergence and growth of 10 species of plants were tested according to US EPA OPPTS 850.4100 and 850.4225. No deviations from the guidelines occurred.	
5.2	**Results and discussion**	There were no apparent adverse treatment-related effects on any of the 10 plant species tested. Differences in seedling emergence and growth between the 225 g a.s./ha treatment group means and the pooled control means were minor and not statistically significant ($p>0.05$).	X
5.2.1	NOEC	225 g a.s./ha for emergence and growth of all species tested	
5.3	**Conclusion**	There were no observed treatment-related effects on any of the test species. Since the greatest difference was a 22% reduction in emergence compared to the pooled control observed in tomato (< 25% detrimental effect or response), no additional testing is ordinarily required and the tested concentration can be taken as the NOEC. For validity criteria see Table A7_5_1_3_01-5.	X
5.3.1	Reliability	1	
5.3.2	Deficiencies	No	

Section 7.5.1.3/01 and 7.5.2.2/01
Annex Point IIIA XIII.3.4

Acute toxicity to plants
Long-term test with terrestrial plants

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
	COMMENTS FROM ... *(specify)*
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	

Table A7_5_1_3_01-1: Test plants

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Section 7.5.1.3/02 Acute toxicity to plants

Annex Point IIIA XIII.3.4

Official use only

1 REFERENCE

1.1	**Reference**	[redacted] (2000b): [redacted]
1.2	**Data protection**	Yes
1.2.1	Data owner	[redacted]
1.2.2	Companies with letter of access	[redacted]
1.2.3	Criteria for data protection	[redacted]

2 GUIDELINES AND QUALITY ASSURANCE

2.1	**Guideline study**	Yes US EPA OPPTS 850.4150
2.2	**GLP**	Yes
2.3	**Deviations**	No

3 METHOD

3.1	**Test material**	TI-435 50% WDG
3.1.1	Lot/Batch number	IW016-046
3.1.2	Specification	[redacted]
3.1.3	Purity	[redacted]
3.1.4	Composition of Product	[redacted]
3.1.5	Further relevant properties	[redacted]
3.1.6	Method of analysis	[redacted]
3.2	**Preparation of TS solution for poorly soluble or volatile test substances**	[redacted]
3.3	**Reference substance**	[redacted]
3.4	**Blank formulation**	[redacted]
3.5	**Testing procedure**	
3.5.1	Preparation of spray mixtures	[redacted]

Section 7.5.1.3/02 **Acute toxicity to plants**
Annex Point IIIA XIII.3.4

[redacted]

3.5.2	Test plants	[redacted]
3.5.3	Test system	[redacted]
3.5.4	Test conditions	[redacted]
3.5.5	Test duration	15 days
3.5.6	Test parameter	Plant growth and condition (phytotoxicity) [redacted]
3.5.7	Sampling	[redacted]
3.5.8	Method of analysis of the plant material	Not relevant. Only height and dry weight of plants were determined.
3.5.9	Statistics	For each species, an assessment was made as to whether the test concentration was a NOEC. Plant growth was assessed by comparing treatment group means for shoot height and dry weight. Evaluation of plant condition was also used in determining treatment related effects. Although group mean plant scores were calculated, statistical comparison of the means was not performed since condition is a qualitative measurement (relative not quantitative differences). A t-test was used to determine if the mean height or dry weight of the treatment group differed significantly from the mean of the pooled controls (water control and formulation blank).

4 RESULTS

4.1	**Results test substance**	
4.1.1	Applied initial concentration	[redacted]
4.1.2	Phytotoxicity rating	[redacted]
4.1.3	Plant height	[redacted]
4.1.4	Plant dry weights	[redacted]
4.1.5	Number of dead plants	[redacted]
4.1.6	Effect data	[redacted]

Section 7.5.1.3/02 Acute toxicity to plants
Annex Point IIIA XIII.3.4

[redacted]

4.1.7	Concentration / response curve	[redacted]
4.1.8	Other effects	[redacted]
4.2	**Results of controls**	
4.2.1	Applied initial concentration	[redacted]
4.2.2	Number/ percentage of plants showing adverse effects	[redacted]
4.3	**Test with reference substance**	[redacted]

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	Toxic effects of TI-435 50% WDG on vegetative vigor of 10 species of plants were tested according to US EPA OPPTS 850.4150. No deviations from the guideline occurred.
5.2	**Results and discussion**	There were no apparent adverse treatment-related effects on any of the 10 plant species tested after application of equivalent 225 g a.s./ha. Differences between treatment group means and the pooled control means were minor and not statistically significant ($p>0.05$).
5.2.1	NOEC	225 g a.s./ha for vegetative vigor of all species tested
5.3	**Conclusion**	There were no observed treatment-related effects on any of the test species. Since the greatest difference between the treatment group and the control was 9% (<25% detrimental effect or response), no additional testing is ordinarily required and the tested concentration can be taken as the NOEC. For validity criteria see Table A7_5_1_3_02-5.
5.3.1	Reliability	1
5.3.2	Deficiencies	No

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]

Section 7.5.1.3/02 Acute toxicity to plants

Annex Point IIIA XIII.3.4

Remarks	The performed test is an acute plant test and can not be submitted as acute and longterm study. Therefore, it should be Section A7.5.1.3/02: Acute toxicity to plants.
	COMMENTS FROM ... *(specify)*
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	

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Section A7.5.2.1/01 Annex Point IIIA XIII.3.2 Reproduction study with earthworms or other soil non-target macro-organisms

Official use only

	1 REFERENCE	
1.1	**Reference**	[redacted] (1999): [redacted]
1.2	**Data protection**	Yes
1.2.1	Data owner	[redacted]
1.2.2	Companies with letter of access	[redacted]
1.2.3	Criteria for data protection	[redacted]
	2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes ISO-Guideline 11268-2 and BBA-Guideline, part VI, 2-2, [redacted]"
2.2	**GLP**	Yes
2.3	**Deviations**	None
	3 METHOD	
3.1	**Test material**	[redacted]
3.1.1	Lot/Batch number	[redacted]
3.1.2	Specification	[redacted]
3.1.3	Purity	[redacted]
3.1.4	Composition of Product	[redacted]
3.1.5	Further relevant properties	[redacted]
3.1.6	Method of analysis	[redacted]
3.2	**Reference substance**	[redacted]
3.2.1	Method of analysis for reference substance	[redacted]
3.3	**Testing procedure**	
3.3.1	Preparation of the test substance	[redacted]
3.3.2	Application of the test substance	[redacted]

Section A7.5.2.1/01 **Reproduction study with earthworms or other soil non-target macro-organisms**
Annex Point IIIA XIII.3.2

[redacted]

3.3.3	Test organisms	[redacted]
3.3.4	Test system	[redacted]
3.3.5	Test conditions	[redacted]
3.3.6	Test duration	[redacted]
3.3.7	Test parameter	[redacted]
3.3.8	Examination	[redacted]
3.3.9	Monitoring of test substance concentration	[redacted]
3.3.10	Statistics	[redacted]

4 RESULTS

4.1	**Results of test substance**	
4.1.1	Application rate	[redacted]
4.1.2	Mortality	[redacted]
4.1.3	Body weights	[redacted]
4.1.4	Reproduction	[redacted]
4.1.5	Other effects	No
4.2	**Results of controls**	
4.2.1	Mortality	[redacted]
4.2.2	Body weights	[redacted]

Section A7.5.2.1/01
Annex Point IIIA XIII.3.2

Reproduction study with earthworms or other soil non-target macro-organisms

4.2.3	Reproduction	[redacted]
4.3	**Test with reference substance**	[redacted]
4.3.1	Concentration	[redacted]
4.3.2	Mortality	[redacted]
4.3.3	Body weights	[redacted]
4.3.4	Reproduction	[redacted]

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	[redacted]
5.2	**Results and discussion**	[redacted]
5.3	**Conclusion**	At application rates up to the maximum field application rate, no negative effects on earthworm reproduction are to be expected. Validity criteria can be considered as fulfilled (see Table A7_5_2_1_01-7). The results of the toxic reference group were within acceptable limits and confirm the validity of the test.
5.3.1	Reliability	1
5.3.2	Deficiencies	No

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	
	COMMENTS FROM ... *(specify)*
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	

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Section A7.5.1.2/02 and A7.5.2.1/02
Annex Point IIIA XIII.3.2

Acute toxicity to earthworms or other soil non-target macro-organisms
Reproduction study with earthworms or other soil non-target macro-organisms

Official use only

	1 REFERENCE	
1.1	**Reference**	[redacted]. (2000[redacted]
1.2	**Data protection**	Yes
1.2.1	Data owner	[redacted]
1.2.2	Companies with letter of access	[redacted]
1.2.3	Criteria for data protection	[redacted]
	2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes ISO/FDIS 11267 (1998)
2.2	**GLP**	Yes
2.3	**Deviations**	No
	3 METHOD	
3.1	**Test material**	[redacted]
3.1.1	Lot/Batch number	[redacted]
3.1.2	Specification	[redacted]
3.1.3	Purity	100%
3.1.4	Composition of Product	[redacted]
3.1.5	Further relevant properties	[redacted]
3.1.6	Method of analysis	Not relevant
3.2	**Reference substance**	Yes [redacted]
3.2.1	Method of analysis for reference substance	Not relevant
3.3	**Testing procedure**	
3.3.1	Preparation of the test substance	[redacted]
3.3.2	Application of the test substance	[redacted]

Section A7.5.1.2/02 and A7.5.2.1/02
Annex Point IIIA XIII.3.2

Acute toxicity to earthworms or other soil non-target macro-organisms

Reproduction study with earthworms or other soil non-target macro-organisms

3.3.3	Test organisms	[redacted]
3.3.4	Test system	[redacted]
3.3.5	Test conditions	[redacted]
3.3.6	Test duration	[redacted]
3.3.7	Test parameter	[redacted]
3.3.8	Examination	[redacted]
3.3.9	Monitoring of test substance concentration	No
3.3.10	Statistics	The LC_{50} for corrected mortality (corrected for mortality in the control according to SCHNEIDER-ORELLI, 1947) and the EC_{50} for inhibition of the reproduction were calculated by Probit analysis. The NOEC and LOEC were determined in comparison to the control group using the one way analysis of variance (ANOVA) and Dunnet's test ($p<0.05$).

4 RESULTS

4.1	**Filter paper test**	[redacted]
4.2	**Soil test**	
4.2.1	Initial concentrations of test substance	[redacted]
4.2.2	Effect data (Mortality)	[redacted]
4.2.3	Concentration / effect curve	[redacted]
4.2.4	Other effects	[redacted]
4.3	**Results of controls**	
4.3.1	Mortality	In the control group, the mean mortality was 2% after 28 days.
4.3.2	Reproduction	In the control group, the mean number of juveniles found was 697 after 28 days.
4.4	**Test with reference substance**	Performed
4.4.1	Concentrations	0.032, 0.1, 0.32, 1.0 and 3.2 mg/kg dw artificial soil

Section A7.5.1.2/02 and A7.5.2.1/02
Annex Point IIIA XIII.3.2

Acute toxicity to earthworms or other soil non-target macro-organisms

Reproduction study with earthworms or other soil non-target macro-organisms

4.4.2	Results	The reference substance LC_{50} values for mortality and reproduction at test termination were determined to be 0.14 and 0.13 mg/kg dw soil, respectively. The NOEC for reproduction was 0.1 mg/kg dw soil. The NOEC for mortality could not be determined. These values indicate an acceptable response of the test system.

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	The toxicity of TI-435 to collembola was tested according to ISO/FDIS 11267 (1998). *Folsomia candida* were exposed to nominal concentrations of 0.01, 0.032, 0.1, 0.32 and 1.0 mg/kg dw artificial soil and effects on mortality and reproduction were observed.
5.2	**Results and discussion**	[redacted]
5.2.1	LC_{50} (mortality)	1.02 mg/kg dw soil (calculated)
5.2.2	LOEC (mortality)	1.0 mg/kg dw soil (nominal)
5.2.3	NOEC (mortality)	0.32 mg/kg dw soil (nominal)
5.2.4	LC_{50} (reproduction)	0.76 mg/kg dw soil (calculated)
5.2.5	LOEC (reproduction)	1.0 mg/kg dw soil (nominal)
5.2.6	NOEC (reproduction)	0.32 mg/kg dw soil (nominal)
5.3	**Conclusion**	Validity criteria can be considered as fulfilled (see validity criteria summarised in Table A7_5_1_2_02-6).
5.3.1	Other Conclusions	
5.3.2	Reliability	1
5.3.3	Deficiencies	No

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
	COMMENTS FROM ... *(specify)*
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	

Table A7_5_1_2_02-1: Test organisms

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Section 7.5.2.2/01
Annex Point IIIA XIII.3.4 **Long-term test with terrestrial plants**

Official use only

	1 REFERENCE	
1.1	**Reference**	[redacted]. (2000a): [redacted]
1.2	**Data protection**	Yes
1.2.1	Data owner	[redacted]
1.2.2	Companies with letter of access	[redacted]
1.2.3	Criteria for data protection	[redacted]
	2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes US EPA OPPTS 850.4100 and 850.4225
2.2	**GLP**	Yes
2.3	**Deviations**	No
	3 METHOD	
3.1	**Test material**	[redacted]
3.1.1	Lot/Batch number	[redacted]
3.1.2	Specification	[redacted]
3.1.3	Purity	[redacted]
3.1.4	Composition of Product	[redacted]
3.1.5	Further relevant properties	None
3.1.6	Method of analysis	[redacted]
3.2	**Preparation of TS solution for poorly soluble or volatile test substances**	[redacted]
3.3	**Reference substance**	No
3.4	**Blank formulation**	[redacted]
3.5	**Testing procedure**	
3.5.1	Preparation of spray mixtures	[redacted]

Section 7.5.2.2/01
Annex Point IIIA XIII.3.4 **Long-term test with terrestrial plants**

[redacted]

3.5.2	Test plants	See Table A7_5_1_3_01-1
3.5.3	Test system	See Table A7_5_1_3_01-2
3.5.4	Test conditions	[redacted]
3.5.5	Test duration	15 days
3.5.6	Test parameter	[redacted]
3.5.7	Sampling	[redacted]
3.5.8	Method of analysis of the plant material	[redacted]
3.5.9	Statistics	[redacted]

4 RESULTS

4.1 Results test substance

4.1.1	Applied initial concentration	Analysis of the spray mixture showed that the test concentration was in the range of 218 - 234 ppm a.s., i.e. 90.9 – 97.4% of nominal (mean: 94.9%).
4.1.2	Phytotoxicity rating	There were no apparent adverse treatment-related effects on any of the 10 plant species tested.
4.1.3	Plant height	[redacted]
4.1.4	Plant dry weights	[redacted]
4.1.5	Emergence	[redacted]
4.1.6	Number of dead plants	[redacted]
4.1.7	Effect data	[redacted]

Section 7.5.2.2/01
Annex Point IIIA XIII.3.4 **Long-term test with terrestrial plants**

		[redacted]
4.1.8	Concentration / response curve	Not relevant (see 4.1.7)
4.1.9	Other effects	None for all species and treatment groups
4.2	**Results of controls**	
4.2.1	Applied initial concentration	[redacted]
4.2.2	Number/ percentage of plants showing adverse effects	[redacted]
4.3	**Test with reference substance**	Not performed

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	Toxic effects of [redacted] on seedling emergence and growth of 10 species of plants were tested according to US EPA OPPTS 850.4100 and 850.4225. No deviations from the guidelines occurred.
5.2	**Results and discussion**	There were no apparent adverse treatment-related effects on any of the 10 plant species tested. Differences in seedling emergence and growth between the 225 g a.s./ha treatment group means and the pooled control means were minor and not statistically significant ($p>0.05$).
5.2.1	NOEC	225 g a.s./ha for emergence and growth of all species tested
5.3	**Conclusion**	There were no observed treatment-related effects on any of the test species. Since the greatest difference was a 22% reduction in emergence compared to the pooled control observed in tomato (< 25% detrimental effect or response), no additional testing is ordinarily required and the tested concentration can be taken as the NOEC. For validity criteria see Table A7_5_1_3_01-5.
5.3.1	Reliability	1
5.3.2	Deficiencies	No

Section 7.5.2.2/01
Annex Point IIIA XIII.3.4 **Long-term test with terrestrial plants**

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	
	COMMENTS FROM ... *(specify)*
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*
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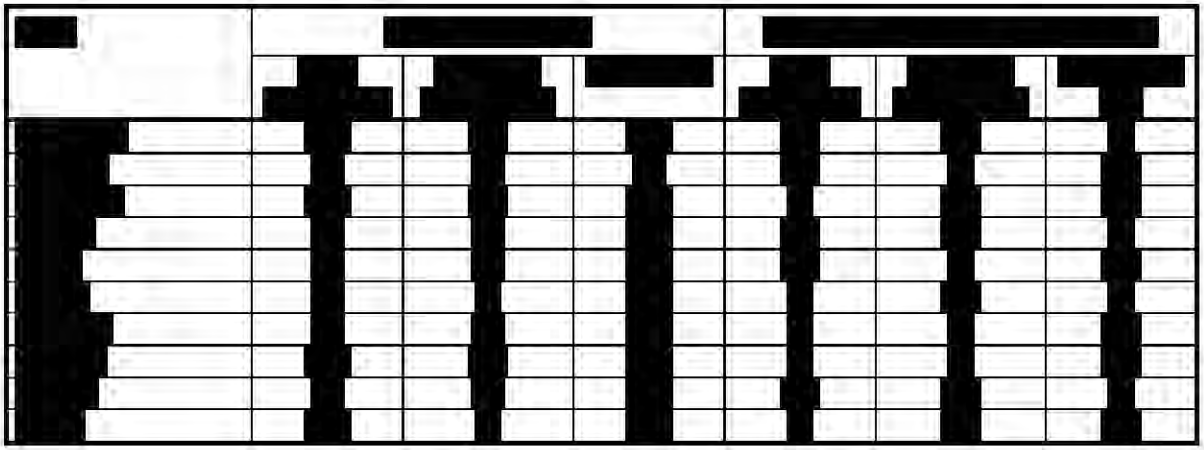

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Section 7.5.2.2/02

Annex Point IIIA XIII.3.4 **Long-term test with terrestrial plants**

Official use only

	1 REFERENCE	
1.1	**Reference**	[redacted] (2000b): [redacted]
1.2	**Data protection**	Yes
1.2.1	Data owner	[redacted]
1.2.2	Companies with letter of access	[redacted]
1.2.3	Criteria for data protection	[redacted]
	2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes US EPA OPPTS 850.4150
2.2	**GLP**	Yes
2.3	**Deviations**	No
	3 METHOD	
3.1	**Test material**	[redacted]
3.1.1	Lot/Batch number	[redacted]
3.1.2	Specification	[redacted]
3.1.3	Purity	[redacted]
3.1.4	Composition of Product	[redacted]
3.1.5	Further relevant properties	None
3.1.6	Method of analysis	[redacted]
3.2	**Preparation of TS solution for poorly soluble or volatile test substances**	[redacted]
3.3	**Reference substance**	[redacted]
3.4	**Blank formulation**	[redacted]
3.5	**Testing procedure**	
3.5.1	Preparation of spray mixtures	[redacted]

Section 7.5.2.2/02
Annex Point IIIA XIII.3.4 **Long-term test with terrestrial plants**

[redacted]

3.5.2 Test plants [redacted]

3.5.3 Test system [redacted]

3.5.4 Test conditions [redacted]

3.5.5 Test duration [redacted]

3.5.6 Test parameter [redacted]

3.5.7 Sampling [redacted]

3.5.8 Method of analysis of the plant material [redacted]

3.5.9 Statistics [redacted]

4 RESULTS

4.1 Results test substance

4.1.1 Applied initial concentration [redacted]

4.1.2 Phytotoxicity rating [redacted]

4.1.3 Plant height [redacted]

4.1.4 Plant dry weights [redacted]

4.1.5 Number of dead plants [redacted]

4.1.6 Effect data [redacted]

Section 7.5.2.2/02
Annex Point IIIA XIII.3.4 **Long-term test with terrestrial plants**

		[redacted]
4.1.7	Concentration / response curve	Not relevant (see 4.1.6)
4.1.8	Other effects	None for all species and treatment groups
4.2	**Results of controls**	
4.2.1	Applied initial concentration	[redacted]
4.2.2	Number/ percentage of plants showing adverse effects	[redacted]
4.3	**Test with reference substance**	Not performed

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	Toxic effects of [redacted] on vegetative vigor of 10 species of plants were tested according to US EPA OPPTS 850.4150. No deviations from the guideline occurred.
5.2	**Results and discussion**	[redacted]
5.2.1	NOEC	225 g a.s./ha for vegetative vigor of all species tested
5.3	**Conclusion**	There were no observed treatment-related effects on any of the test species. Since the greatest difference between the treatment group and the control was 9% (< 25% detrimental effect or response), no additional testing is ordinarily required and the tested concentration can be taken as the NOEC. For validity criteria see Table A7_5_1_3_02-5.
5.3.1	Reliability	1
5.3.2	Deficiencies	No

Section 7.5.2.2/02
Annex Point IIIA XIII.3.4 **Long-term test with terrestrial plants**

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	
	COMMENTS FROM ... *(specify)*
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	

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