Table A7_5_1_1-3: Test system

Criteria	Details
Culturing apparatus	1.5 L Glass jars
Number of vessels / concentration	At least 4 at each concentration
Aeration device	None specified
Measuring equipment	BSB digi (Fa Johanna Otto)
Test performed in closed vessels	Not stated

Table A7_5_1_1-4: Application of test substance

Criteria	Details
Application procedure	0.56 mg/kg (1x): 42.0 mg of BF 222-ETU were dissolved in 250 mL of distilled water. 10 mL of this solution were added to the soil as part of the calculated addition of water necessary to achieve 45% of the soil's maximum water holding capacity to give an application rate of 0.56 mg BF 222-ETU/kg dry soil. 5.6 mg/kg (10x): 84.0 mg of BF 222-ETU were dissolved in 50 mL of distilled water. 10 mL of this solution were added to the soil as part of the calculated addition of water necessary to achieve 45% of the soil's maximum water holding capacity to give an application rate of 5.6 mg BF 222-ETU/kg dry soil.
Carrier	Distilled Water
Concentration of liquid carrier [% v/v]	Included in the quantity of water added to give a WHC of 45%
Liquid carrier control	Water was added to the control to give a WHC of 45%.
Other procedures	None stated

Table A7_5_1_1-5: Test conditions

Criteria	Details
Organic substrate	Glucose
Incubation temperature	20±2°C
Soil moisture	No further adjustments to soil moisture content were made after the addition of water to give a WHC of 45% at the start of the study
Method of soil incubation	The samples were incubated individually
Aeration	Not specified

Table A7_5_1_1-6: Effects of BF 222-ETU on Carbon Transformation in a Loamy Sand Soil over 29 Days

Variant	Days after applicaüon			
	0	**7**	**14**	**29**
Control*	10.2	8.8	7.3	7.1
0.56mg BF 222-ETU/kg dry soil*	9.5	7.9	6.8	6.6
% deviation from control**	-6.86	-10.23	-6.85	-7.04
5.6 mg BF 222-ETU/kg dry soil*	9.4	8.2	6.6	6.7
% deviation from control**	-7.84	-6.82	-9.59	-5.83

*Values reported are the mean of 4 measurements and are given as mg O_2/kg dry soil/h

$$**\%\ \text{Deviation} = \frac{\text{Treated - untreated soil}}{\text{untreated soil}} \times 100$$

Table A7_5_1_1-7: Summary of Effects of BF 222-ETU on Carbon Transformation in a Loamy Sand Soil after 29 Days

Soil	% Deviation from Control**	
	0.56 mg BF 222-ETU/kg dry soil	5.6 mg BF 222-ETU/kg dry soil
Loamy Sand	-7.04	-5.63

+ = stimulation; - = inhibition

$$^{**}\%\ \text{Deviation} = \frac{\text{Treated - untreated soil}}{\text{untreated soil}} \times 100$$

Section A7.5.1.1(2) Inhibition to microbial activity (terrestrial)

Annex Point IIA7.4

Effect of BF 222-ETU on Nitrogen Transformation of the Soil Microflora

IUCLID 4.4/03

Official use only

		1 REFERENCE
1.1	**Reference**	Kreig, W., (2001b) Effect of BF 222-ETU on Nitrogen Transformation of the Soil Microflora, BASF Aktiengesellschaft, BASF Agricultural Centre Limburgerhof, Crop Protection Division, Ecology and Environmental Analytics, P.O. Box 120, 67114 Limburgerhof, Germany, Report No. 97481, 12 January 2001.
1.2	**Data protection**	Yes
1.2.1	Data owner	BASF
1.2.2		
1.2.3	Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I
		2 GUIDELINES AND QUALITY ASSURANCE
2.1	**Guideline study**	Yes OECD-Guideline 216. Soil Microorganisms: Nitrogen Transformation Test
2.2	**GLP**	Yes
2.3	**Deviations**	Yes Soil characterisation was not adequately detailed in the submitted report with respect to sampling site (location, use pattern and sampling depth) and % sand composition. This is considered a minor deviation with no impact on the conclusions of the study.
		3 MATERIALS AND METHODS
3.1	**Test material**	BF 222-ETU
3.1.1	Lot/Batch number	01743-165 (PCP06001)
3.1.2	Specification	Deviating from specification given in section 2 as follows:- The test substance is a metabolite of BAS 222 F
3.1.3	Purity	99.9%
3.1.4	Composition of Product	Not applicable
3.1.5	Further relevant properties	None stated.
3.1.6	Method of analysis	Not applicable
3.2	**Reference substance**	No concurrent test with reference substance was performed.
3.2.1	Method of analysis for reference substance	Not applicable
3.3	**Testing procedure**	

Section A7.5.1.1(2) Inhibition to microbial activity (terrestrial)

Annex Point IIA7.4 **Effect of BF 222-ETU on Nitrogen Transformation of the Soil Microflora**

IUCLID 4.4/03

3.3.1	Soil sample / inoculum / test organism	A loamy sand soil was used (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	TS was applied in distilled water. See table A7_5_1_1-4.
3.3.4	Test conditions	Aerobic at 20±2°C with soil containing water at 45% WHC at the start of the study. See table A7_5_1_1-5.
3.3.5	Test parameter	Ammonification and nitrification
3.3.6	Analytical parameter	NH_4-N and NO_3-N measurement using an ammonia electrode and a nitrate electrode.
3.3.7	Duration of the test	28 Days
3.3.8	Sampling	Days 0, 7, 14 and 28
3.3.9	Monitoring of TS concentration	No
3.3.10	Controls	Controls were prepared without test substance. The control samples comprised of soil, lucerne meal and water.
3.3.11	Statistics	Statistical analysis was limited to calculation of means, standard deviations and % deviation from the mean.
		4 RESULTS
4.1	**Range finding test**	Not performed
4.1.1	Concentration	Not applicable
4.1.2	Effect data	Not applicable
4.2	**Results test substance**	
4.2.1	Initial concentrations of test substance	0.56 mg BF 222-ETU/kg dry test soil, equivalent to 0.42 kg BF 222-ETU/hectare 5.6 mg BF 222-ETU/kg dry test soil, equivalent to 4.2 kg BF 222-ETU/hectare
4.2.2	Actual concentrations of test substance	Not measured
4.2.3	Growth curves	Not applicable
4.2.4	Cell concentration data	Not applicable
4.2.5	Concentration/ response curve	Not applicable
4.2.6	Effect data	Refer to Table A7_5_1_1-6 for results of tests and effects of BF 222-ETU relative to control over 28 days and to Table A7_5_1_1-7 for a summary of the study. The test substance was found to have a NOEC of 5.6 mg/kg dry soil with respect to nitrogen transformation by soil microflora. This rate was based on the maximum rate of production of BF 222-ETU from the

		active substance BAS 222 F if applied at l0x the maximum field rate of 2.80 kg a.i./hectare).
4.2.7	Other observed effects	None
4.3	**Results of controls**	Refer to Table A7_5_1_1-6
4.4	**Test with reference substance**	No concurrent test with reference substance was performed
4.4.1	Concentrations	Not applicable
4.4.2	Results	Not applicable

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	The effects of BF 222-ETU, a metabolite of BAS 222 F, on nitrogen transformation in soil were examined in a typical agricultural soil during a 28 day exposure in a laboratory study. The soil was a loamy sand of pH 6.2, containing 0.93% organic carbon of which 1.96% was microbial biomass. The soil was divided into 3 groups: control soil, soil treated with 0.56 mg BF 222-ETU/kg (corresponding to an application rate of 2.80 kg a.i./hectare for the active substance BAS 222 F) and soil treated with 5.6 mg BF 222-ETU/kg (corresponding to an application rate of 28.0 kg a.i./hectare for the active substance BAS 222 F). NH_4-nitrogen formed from organically bound nitrogen and NO_3-nitrogen from the nitrification process was determined by using calibrated ion-sensitive electrodes and the Orion expandable ion analyser EA 940.
5.2	**Results and discussion**	The test substance was applied to soil at a rate of 0.56 mg/kg (corresponding to the maximum transformation rate from the active substance BAS 222 F if applied at the maximum field rate of 2.80 kg a.i./hectare) and 5.6 mg/kg soil (corresponding to the maximum transformation rate from the active substance BAS 222 F if applied at l0x the maximum field rate of 2.80 kg a.i./hectare). Neither application rate had a significant effect on nitrogen transformation rates in the soil relative to the study control over 28 days as judged by measurement of nitrate concentrations using a nitrate electrode.
5.2.1	NOEC	5.6 mg BF 222-ETU/kg dry soil
5.2.2	EC_{10}	Not applicable
5.2.3	EC_{50}	Not applicable
5.3	**Conclusion**	BF 222-ETU applied at rates anticipated as arising from application of lx and l0x the maximum application rates of the a.i. BAS 222 F had no significant effect on nitrogen transformation in Lucerne-amended soil.
5.3.1	Reliability	1
5.3.2	Deficiencies	No

Section A7.5.1.1(2) Inhibition to microbial activity (terrestrial)

Annex Point IIA7.4 **Effect of BF 222-ETU on Nitrogen Transformation of the Soil Microflora**

IUCLID 4.4/03

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*Give month and year of evaluation or comments*
Materials and Methods	*State if the applicant's version is acceptable or indicate relevant discrepancies referring to the (sub) heading numbers and to applicant's summary and conclusion.*
Results and discussion	*Adopt applicant's version or include revised version. If necessary, discuss relevant deviations from applicant's view referring to the (sub)heading numbers*
Conclusion	*Adopt applicant's version or include revised version*
Reliability	*Based on the assessment of materials and methods include appropriate reliability indicator*
Acceptability	acceptable / not acceptable *(give reasons if necessary, e.g. if a study is considered acceptable despite a poor reliability indicator. Discuss the relevance of deficiencies and indicate if repeat is necessary.)*
Remarks	
	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	

Table A7_5_1_1-1: Microbial sample / Inoculum (*if applicable; include separate table for different samples*)

<table>
<tr><th>Criteria</th><th>Details</th></tr>
<tr><td>Nature</td><td>Soil sample</td></tr>
<tr><td>Sampling site:</td><td>Not stated</td></tr>
<tr><td>Geographical reference on the sampling site</td><td>Not stated</td></tr>
<tr><td>Data on the history of the site</td><td>Site not treated with plant protection products or fertilizers</td></tr>
<tr><td>Use pattern</td><td>Agricultural soil</td></tr>
<tr><td>Depth of sampling [cm]</td><td>Not stated</td></tr>
<tr><td>Sand / Silt / Clay content [% dry weight]</td><td>Loamy Sand, composition detailed below:-
<table>
<tr><th colspan="2">Particle Size (%)</th></tr>
<tr><td>2000 to ≥ 630 µm</td><td>5.4</td></tr>
<tr><td>630 to ≥ 200 µm</td><td>43.0</td></tr>
<tr><td>200 to ≥ 63 µm</td><td>25.6</td></tr>
<tr><td>63 to ≥ 20 µm</td><td>10.3</td></tr>
<tr><td>20 to ≥ 6.3 µm</td><td>6.5</td></tr>
<tr><td>6.3 to ≥ 2 µm</td><td>4.1</td></tr>
<tr><td><2 µm</td><td>5.3</td></tr>
<tr><td>Soil Type (DIN 4220)</td><td>SI Loamy Sand
Lehmiger Sand</td></tr>
</table></td></tr>
<tr><td>pH</td><td>pH 6.2</td></tr>
<tr><td>Organic carbon content [% dry weight]</td><td>0.93%</td></tr>
<tr><td>Nitrogen content [% dry weight]</td><td>0.07% (prior to addition of lucerne)</td></tr>
<tr><td>Cation exchange capacity [mmol/kg]</td><td>6.6 mval Ba/100g dry weight</td></tr>
<tr><td>Initial microbial biomass</td><td>1.96% (Calculated from reported data)</td></tr>
<tr><td>Reference of methods</td><td>Pipette Method</td></tr>
<tr><td>Collection / storage of samples</td><td>Following mixing, each soil treatment group was distributed into sufficient 1.5 L glass jars to allow 3 replicates at each time-point. 3 replicates of 57.2 g (corresponding to 50 g dry soil) from each group were used to generate the day 0 carbon transformation values. The remainder of the samples were then stored, loosely covered with lids, in a temperature controlled incubator at 20±2°C until sampling at 7, 14 and 28 days. Sampling and analysis were performed with 3 replicates of 57.2 g (corresponding to 50 g dry soil) from each group.</td></tr>
<tr><td>Preparation of inoculum for exposure</td><td>Not applicable</td></tr>
<tr><td>Pretreatment</td><td>Water was added to bring the moisture content of each soil group to 45% of it's maximum water holding capacity.
Control: 67.8 g water were added to and mixed with</td></tr>
</table>

	1648.4 g of soil. Treated: 57.8 g water plus 10 g water containing BF 222-ETU were added to and mixed with 1648.4 g of soil.

Table A7_5_1_1-2: Test organism (*if applicable*)

Criteria	Details
Species	Not applicable
Strain	Not applicable
Source	Not applicable
Sampling site	Not applicable
Laboratory culture	Not applicable
Method of cultivation	Not applicable
Preparation of inoculum for exposure	Not applicable
Pretreatment	Not applicable
Initial cell concentration	Not applicable

Table A7_5_1_1-3: Test system

Criteria	Details
Culturing apparatus	1.5 L Glass jars
Number of vessels / concentration	At least 4 at each concentration
Aeration device	None specified
Measuring equipment	Expandable Ion Analyser EA 940, Orion Res., Cambridge Ammonia Electrode, model 95-12-00, Orion Res., Cambridge Nitrate electrode, model 93-07-00, Orion Res., Cambridge
Test performed in closed vessels	Jars loosely covered with lid to allow air exchange

Table A7_5_1_1-4: Application of test substance

Criteria	Details
Application procedure	0.56 mg/kg (1x): 21.0 mg of BF 222-ETU were dissolved in 250 mL of distilled water. 10 mL of this solution were added to the soil as part of the calculated addition of water necessary to achieve 45% of the soil's maximum water holding capacity to give an application rate of 0.56 mg BF 222-ETU/kg dry soil. 5.6 mg/kg (10x): 84.0 mg of BF 222-ETU were dissolved in 100 mL of distilled water. 10 mL of this solution were added to the soil as part of the calculated addition of water necessary to achieve 45% of the soil's maximum water holding capacity to give an application rate of 5.6 mg BF 222-ETU/kg dry soil.
Carrier	Distilled Water
Concentration of liquid carrier [% v/v]	Included in the quantity of water added to give a WHC of 45%
Liquid carrier control	Water was added to the control to give a WHC of 45%.
Other procedures	None stated

Table A7_5_1_1-5: Test conditions

Criteria	Details
Organic substrate	Lucerne meal (Li-hol) containing 35.1% organic carbon/3.1% nitrogen (dry weight) was used. 7.5 g Lucerne meal were added to 1.5 kg equivalents of dry weight soil, resulting in 0.5% meal in soil and 15.5mg N/100 g of dry weight soil.
Incubation temperature	20±2°C Individual measurements were not provided.
Soil moisture	No further adjustments to soil moisture content were made after the addition of water to give a WHC of 45% at the start of the study
Method of soil incubation	The soil samples were incubated whilst stored in glass jars.
Aeration	The jars were loosely covered by the lids to allow air exchange. No additional aeration was provided.

Table A7_5_1_1-6: Effects of BF 222-ETU on Nitrogen Transformation in a Loamy Sand Soil over 28 Days

Variant	Days after applicaüon			
	0	7	14	28
Control*	20.0	5.43	3.17	2.18
0.56mg BF 222-ETU/kg dry soil*	21.4	5.77	3.37	2.29
% deviation from control**	+7.00	+6.26	+6.31	+5.05
5.6 mg BF 222-ETU/kg dry soil*	21.0	3.86	3.37	2.31
% deviation from control**	+5.00	-28.91	+6.31	+5.93

*Values reported are the mean of 3 measurements and are given as mg NO_3-N/kg dry soil/day

$$**\%\ \text{Deviation} = \frac{\text{Treated - untreated soil}}{\text{untreated soil}} \times 100$$

Table A7_5_1_1-7: Summary of Effects of BF 222-ETU on Nitrogen Transformation in a Loamy Sand Soil after 28 Days

Soil	% Deviation from Control**	
	0.56 mg BF 222-ETU/kg dry soil	5.6 mg BF 222-ETU/kg dry soil
Loamy Sand	+5.05	+5.96

+ = stimulation; - = inhibition

$$**\%\ \text{Deviation} = \frac{\text{Treated - untreated soil}}{\text{untreated soil}} \times 100$$

Section A7.5.1.1(3) Inhibition to microbial activity (terrestrial)

Annex Point IIA7.4

Effect of BF 222-EU on Carbon Transformation of the Soil Microflora

IUCLID 4.4/04

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		1 REFERENCE
1.1	**Reference**	Kreig, W., (2001c) Effect of BF 222-EU on Carbon Transformation of the Soil Microflora, BASF Aktiengesellschaft, BASF Agricultural Centre Limburgerhof, Crop Protection Division, Ecology and Environmental Analytics, P.O. Box 120, 67114 Limburgerhof, Germany, Report No. 99453, 9 February 2001.
1.2	**Data protection**	Yes
1.2.1	Data owner	BASF
1.2.2		
1.2.3	Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I
		2 GUIDELINES AND QUALITY ASSURANCE
2.1	**Guideline study**	Yes OECD-Guideline 217. Soil Microorganisms: Carbon Transformation Test
2.2	**GLP**	Yes
2.3	**Deviations**	Yes Due to technical difficulties with the carbon transformation test on day 28 of the study, the final timepoint reported was Day 29. Soil characterisation was not adequately detailed in the submitted report with respect to sampling site (location, use pattern and sampling depth) and % sand composition. These are considered minor deviations with no impact on the conclusions of the study.
		3 MATERIALS AND METHODS
3.1	**Test material**	BF 222-EU
3.1.1	Lot/Batch number	01743-161 (PCP05998)
3.1.2	Specification	Deviating from specification given in section 2 as follows:- The test substance is a metabolite of BAS 222 F
3.1.3	Purity	88.6%
3.1.4	Composition of Product	Not applicable
3.1.5	Further relevant properties	None stated in the report.
3.1.6	Method of analysis	Not applicable
3.2	**Reference substance**	No concurrent test with reference substance was performed
3.2.1	Method of analysis for reference	Not applicable

	substance	
3.3	**Testing procedure**	
3.3.1	Soil sample / inoculum / test organism	A loamy sand soil was used (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	TS was applied in distilled water. See table A7_5_1_1-4.
3.3.4	Test conditions	Aerobic at 20±2°C with soil containing water at 45% WHC at the start of the study. See table A7_5_1_1-5.
3.3.5	Test parameter	Carbon transformation
3.3.6	Analytical parameter	Glucose induced O_2 consumption
3.3.7	Duration of the test	29 Days
3.3.8	Sampling	Days 0, 7, 14 and 29
3.3.9	Monitoring of TS concentration	No
3.3.10	Controls	Controls were prepared to contain soil and water
3.3.11	Statistics	No formal statistical calculations were applied. The mean glucose-induced oxygen consumption was calculated from 4 replicates in each group at each timepoint. Results from treated soil were expressed as % deviation from the untreated control soil. The standard deviation for each set of data was calculated to ensure the variation between replicates was less than 15%.
		4 RESULTS
4.1	**Range finding test**	Not performed
4.1.1	Concentration	Not applicable
4.1.2	Effect data	Not applicable
4.2	**Results test substance**	
4.2.1	Initial concentrations of test substance	0.56 mg BF 222-EU/kg dry test soil, equivalent to 0.42 kg BF 222-EU/hectare 5.6 mg BF 222-EU/kg dry test soil, equivalent to 4.2 kg BF 222-EU/hectare
4.2.2	Actual concentrations of test substance	Not measured
4.2.3	Growth curves	Not applicable
4.2.4	Cell concentration data	Not applicable
4.2.5	Concentration/ response curve	Not applicable

Section A7.5.1.1(3) **Inhibition to microbial activity (terrestrial)**

Annex Point IIA7.4 **Effect of BF 222-EU on Carbon Transformation of the Soil Microflora**

IUCLID 4.4/04

4.2.6	Effect data	Refer to Table A7_5_1_1-6 for results of the glucose-induced oxygen consumption tests and effects of BF 222-EU relative to control over 29 days and to Table A7_5_1_1-7 for a summary of the study. The test substance was found to have a NOEC of 5.6 mg/kg dry soil with respect to carbon transformation by soil microflora. This rate was based on the maximum rate of production of BF 222-EU from the active substance BAS 222 F if applied at l0x the maximum field rate of 2.80 kg a.i./hectare).
4.2.7	Other observed effects	None
4.3	**Results of controls**	Refer to Table A7_5_1_1-6
4.4	**Test with reference substance**	No concurrent test with reference substance was performed
4.4.1	Concentrations	Not applicable
4.4.2	Results	Not applicable

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	The effects of BF 222-EU, a metabolite of BAS 222 F, on carbon transformation in soil were examined in a typical agricultural soil during a 29 day exposure in a laboratory study. The soil was a loamy sand of pH 6.2, containing 0.93% organic carbon of which 1.96% was microbial biomass. The soil was divided into 3 groups: control soil, soil treated with 0.56 mg BF 222-EU/kg (corresponding to an application rate of 2.80 kg a.i./hectare for the active substance BAS 222 F) and soil treated with 5.6 mg BF 222-EU/kg (corresponding to an application rate of 28.0 kg a.i./hectare for the active substance BAS 222 F). Carbon transformation was determined in 4 replicates per soil group at a series of timepoints through measurement of glucose-induced oxygen consumption.
5.2	**Results and discussion**	The test substance was applied to soil at a rate of 0.56 mg/kg (corresponding to the maximum transformation rate from the active substance BAS 222 F if applied at the maximum field rate of 2.80 kg a.i./hectare) and 5.6 mg/kg soil (corresponding to the maximum transformation rate from the active substance BAS 222 F if applied at l0x the maximum field rate of 2.80 kg a.i./hectare). Neither application rate had a significant effect on carbon transformation rates in the soil relative to the study control over 29 days as judged by measurement of glucose-induced oxygen consumption.
5.2.1	NOEC	5.6 mg BF 222-EU/kg dry soil
5.2.2	EC_{10}	Not applicable
5.2.3	EC_{50}	Not applicable
5.3	**Conclusion**	BF 222-EU applied at rates anticipated as arising from application of lx and l0x the maximum application rates of the a.i. BAS 222 F had no significant effect on carbon transformation by soil microflora.

Section A7.5.1.1(3) Inhibition to microbial activity (terrestrial)

Annex Point IIA7.4 **Effect of BF 222-EU on Carbon Transformation of the Soil Microflora**

IUCLID 4.4/04

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	*Give month and year of evaluation or comments*
Materials and Methods	*State if the applicant's version is acceptable or indicate relevant discrepancies referring to the (sub) heading numbers and to applicant's summary and conclusion.*
Results and discussion	*Adopt applicant's version or include revised version. If necessary, discuss relevant deviations from applicant's view referring to the (sub)heading numbers*
Conclusion	*Adopt applicant's version or include revised version*
Reliability	*Based on the assessment of materials and methods include appropriate reliability indicator*
Acceptability	acceptable / not acceptable *(give reasons if necessary, e.g. if a study is considered acceptable despite a poor reliability indicator. Discuss the relevance of deficiencies and indicate if repeat is necessary.)*
Remarks	
	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	

Table A7_5_1_1-1: Microbial sample / Inoculum (*if applicable; include separate table for different samples*)

<table>
<tr><th>Criteria</th><th>Details</th></tr>
<tr><td>Nature</td><td>Soil sample</td></tr>
<tr><td>Sampling site:</td><td>Not stated</td></tr>
<tr><td>Geographical reference on the sampling site</td><td>Not stated</td></tr>
<tr><td>Data on the history of the site</td><td>Site not treated with plant protection products or fertilizers</td></tr>
<tr><td>Use pattern</td><td>Not stated</td></tr>
<tr><td>Depth of sampling [cm]</td><td>Not stated</td></tr>
<tr><td>Sand / Silt / Clay content [% dry weight]</td><td>Loamy Sand, composition detailed below:-
<table>
<tr><th colspan="2">Particle Size (%)</th></tr>
<tr><td>2000 to ≥ 630 µm</td><td>5.4</td></tr>
<tr><td>630 to ≥ 200 µm</td><td>43.0</td></tr>
<tr><td>200 to ≥ 63 µm</td><td>25.6</td></tr>
<tr><td>63 to ≥ 20 µm</td><td>10.3</td></tr>
<tr><td>20 to ≥ 6.3 µm</td><td>6.5</td></tr>
<tr><td>6.3 to ≥ 2 µm</td><td>4.1</td></tr>
<tr><td><2 µm</td><td>5.3</td></tr>
<tr><td>Soil Type (DIN 4220)</td><td>SI Loamy Sand
Lehmiger Sand</td></tr>
</table></td></tr>
<tr><td>pH</td><td>pH 6.2</td></tr>
<tr><td>Organic carbon content [% dry weight]</td><td>0.93%</td></tr>
<tr><td>Nitrogen content [% dry weight]</td><td>0.07%</td></tr>
<tr><td>Cation exchange capacity [mmol/kg]</td><td>6.6 mval Ba/100g dry weight</td></tr>
<tr><td>Initial microbial biomass</td><td>1.96% (Calculated from reported data)</td></tr>
<tr><td>Reference of methods</td><td>Respiratory activity in the soil was determined by the indirect calculation of oxygen consumed in the course of the test. Carbon dioxide produced in the course of respiration is bound by a CO absorber, meaning that there is a negative pressure change in the vessel related to the consumption of oxygen. Reduction in pressure causes the closure of a contact which results in the electrolytic generation of oxygen until pressure is restored. The device used (BSB digi) measures the amount of electricity consumed over the course of the test and using the Faraday law relates this to the quantity of oxygen required to maintain equilibrium in the system. This equates to eh amount of oxygen consumed in by respiration in the system.</td></tr>
<tr><td>Collection / storage of samples</td><td>Following mixing, each soil treatment group was distributed into sufficient 1.5 L glass jars to allow 4 replicates at each time-point. 4 replicates of each group were used to generate the day 0 carbon transformation values. The remainder of the samples</td></tr>
</table>

	were then stored in a temperature controlled incubator at 20±2°C until sampling at 7, 14 and 29 days. Measurements of glucose-induced O_2 consumption were made over a period of 12 hours at 20±2°C using a BSB digi on samples taken at days 0, 7, 14 and 29.
Preparation of inoculum for exposure	Not applicable
Pretreatment	Water was added to bring the moisture content of each soil group to 45% of it's maximum water holding capacity. Control: 102.9 g water were added to and mixed with 3329.6 g of soil Treated: 92.9 g water plus 10 g water containing BF 222-EU were added to and mixed with 3329.6 g of soil

Table A7_5_1_1-2: Test organism (*if applicable*)

Criteria	**Details**
Species	Not applicable
Strain	Not applicable
Source	Not applicable
Sampling site	Not applicable
Laboratory culture	Not applicable
Method of cultivation	Not applicable
Preparation of inoculum for exposure	Not applicable
Pretreatment	Not applicable
Initial cell concentration	Not applicable

Table A7_5_1_1-3: Test system

Criteria	**Details**
Culturing apparatus	1.5 L Glass jars
Number of vessels / concentration	At least 4 at each concentration
Aeration device	None specified
Measuring equipment	BSB digi (Fa Johanna Otto)
Test performed in closed vessels	Not stated

Table A7_5_1_1-4: Application of test substance

Criteria	Details
Application procedure	0.56 mg/kg (1x): 42.0 mg of BF 222-EU were dissolved in 250 mL of distilled water. 10 mL of this solution were added to the soil as part of the calculated addition of water necessary to achieve 45% of the soil's maximum water holding capacity to give an application rate of 0.56 mg BF 222-EU/kg dry soil. 5.6 mg/kg (10x): 84.0 mg of BF 222-EU were dissolved in 50 mL of distilled water. 10 mL of this solution were added to the soil as part of the calculated addition of water necessary to achieve 45% of the soil's maximum water holding capacity to give an application rate of 5.6 mg BF 222-EU/kg dry soil.
Carrier	Distilled Water
Concentration of liquid carrier [% v/v]	Included in the quantity of water added to give a WHC of 45%
Liquid carrier control	Water was added to the control to give a WHC of 45%.
Other procedures	None stated

Table A7_5_1_1-5: Test conditions

Criteria	Details
Organic substrate	Glucose
Incubation temperature	20±2°C
Soil moisture	No further adjustments to soil moisture content were made after the addition of water to give a WHC of 45% at the start of the study
Method of soil incubation	The samples were incubated individually
Aeration	Not specified

Table A7_5_1_1-6: Effects of BF 222-EU on Carbon Transformation in a Loamy Sand Soil over 29 Days

Variant	Days after applicaüon			
	0	7	14	29
Control*	10.8	9.3	7.4	7.6
0.56mg BF 222-EU/kg dry soil*	10.3	8.8	6.8	7.3
% deviation from control**	-4.63	-5.38	-8.11	-3.95
5.6 mg BF 222-EU/kg dry soil*	10.1	8.8	7.1	7.3
% deviation from control**	-6.48	-5.38	-4.05	-3.95

*Values reported are the mean of 4 measurements and are given as mg O_2/kg dry soil/h

$$**\%\ \text{Deviation} = \frac{\text{Treated - untreated soil}}{\text{untreated soil}} \times 100$$

Table A7_5_1_1-7: Summary of Effects of BF 222-EU on Carbon Transformation in a Loamy Sand Soil after 29 Days

Soil	% Deviation from Control**	
	0.56 mg BF 222-EU/kg dry soil	5.6 mg BF 222-EU/kg dry soil
Loamy Sand	-3.95	-3.95

+ = stimulation; - = inhibition

$$**\%\ \text{Deviation} = \frac{\text{Treated - untreated soil}}{\text{untreated soil}} \times 100$$

Section A7.5.1.1(4) Inhibition to microbial activity (terrestrial)

Annex Point IIA7.4 **Effect of BF 222-EU on Nitrogen Transformation of the Soil Microflora**

IUCLID 4.4/05

Official use only

		1 REFERENCE
1.1	**Reference**	Kreig, W., (2001d) Effect of BF 222-EU on Nitrogen Transformation of the Soil Microflora, BASF Aktiengesellschaft, BASF Agricultural Centre Limburgerhof, Crop Protection Division, Ecology and Environmental Analytics, P.O. Box 120, 67114 Limburgerhof, Germany, Report No. 97455, 12 January 2001.
1.2	**Data protection**	Yes
1.2.1	Data owner	BASF
1.2.2		
1.2.3	Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I
		2 GUIDELINES AND QUALITY ASSURANCE
2.1	**Guideline study**	Yes OECD-Guideline 216. Soil Microorganisms: Nitrogen Transformation Test
2.2	**GLP**	Yes
2.3	**Deviations**	Yes Soil characterisation was not adequately detailed in the submitted report with respect to sampling site (location, use pattern and sampling depth) and % sand composition. This is considered a minor deviation with no impact on the conclusions of the study.
		3 MATERIALS AND METHODS
3.1	**Test material**	BF 222-EU
3.1.1	Lot/Batch number	01743-161 (PCP05998)
3.1.2	Specification	Deviating from specification given in section 2 as follows:- The test substance is a metabolite of BAS 222 F
3.1.3	Purity	88.6
3.1.4	Composition of Product	Not applicable
3.1.5	Further relevant properties	None stated in the report.
3.1.6	Method of analysis	Not applicable
3.2	**Reference substance**	No concurrent test with reference substance was performed
3.2.1	Method of analysis for reference substance	Not applicable
3.3	**Testing procedure**	

Section A7.5.1.1(4) **Inhibition to microbial activity (terrestrial)**

Annex Point IIA7.4 **Effect of BF 222-EU on Nitrogen Transformation of the Soil Microflora**

IUCLID 4.4/05

3.3.1	Soil sample / inoculum / test organism	A loamy sand soil was used (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	TS was applied in distilled water. See table A7_5_1_1-4.
3.3.4	Test conditions	Aerobic at 20±2°C with soil containing water at 45% WHC at the start of the study. See table A7_5_1_1-5.
3.3.5	Test parameter	Ammonification and nitrification
3.3.6	Analytical parameter	NH_4-N and NO_3-N measurement using an ammonia electrode and a nitrate electrode.
3.3.7	Duration of the test	28 Days
3.3.8	Sampling	Days 0, 7, 14 and 28
3.3.9	Monitoring of TS concentration	No
3.3.10	Controls	Controls were prepared without test substance. The control samples comprised of soil, lucerne meal and water.
3.3.11	Statistics	Statistical analysis was limited to calculation of means, standard deviations and % deviation from the mean.
		4 RESULTS
4.1	**Range finding test**	Not performed
4.1.1	Concentration	Not applicable
4.1.2	Effect data	Not applicable
4.2	**Results test substance**	
4.2.1	Initial concentrations of test substance	0.56 mg BF 222-EU/kg dry test soil, equivalent to 0.42 kg BF 222-EU/hectare 5.6 mg BF 222-EU/kg dry test soil, equivalent to 4.2 kg BF 222-EU/hectare
4.2.2	Actual concentrations of test substance	Not measured
4.2.3	Growth curves	Not applicable
4.2.4	Cell concentration data	Not applicable
4.2.5	Concentration/ response curve	Not applicable
4.2.6	Effect data	Refer to Table A7_5_1_1-6 for results of tests and effects of BF 222-EU relative to control over 28 days and to Table A7_5_1_1-7 for a summary of the study. The test substance was found to have a NOEC of 5.6 mg/kg dry soil with respect to nitrogen transformation by soil microflora. This rate was based on the maximum rate of production of BF 222-EU from the active

		substance BAS 222 F if applied at l0x the maximum field rate of 2.80 kg a.i./hectare).
4.2.7	Other observed effects	None
4.3	**Results of controls**	Refer to Table A7_5_1_1-6
4.4	**Test with reference substance**	No concurrent test with reference substance was performed
4.4.1	Concentrations	Not applicable
4.4.2	Results	Not applicable

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	The effects of BF 222-EU, a metabolite of BAS 222 F, on nitrogen transformation in soil were examined in a typical agricultural soil during a 28 day exposure in a laboratory study. The soil was a loamy sand of pH 6.2, containing 0.93% organic carbon of which 1.96% was microbial biomass. The soil was divided into 3 groups: control soil, soil treated with 0.56 mg BF 222-EU/kg (corresponding to an application rate of 2.80 kg a.i./hectare for the active substance BAS 222 F) and soil treated with 5.6 mg BF 222-EU/kg (corresponding to an application rate of 28.0 kg a.i./hectare for the active substance BAS 222 F). NH_4-nitrogen formed from organically bound nitrogen and NO_3-nitrogen from the nitrification process was determined by using calibrated ion-sensitive electrodes and the Orion expandable ion analyser EA 940.
5.2	**Results and discussion**	The test substance was applied to soil at a rate of 0.56 mg/kg (corresponding to the maximum transformation rate from the active substance BAS 222 F if applied at the maximum field rate of 2.80 kg a.i./hectare) and 5.6 mg/kg soil (corresponding to the maximum transformation rate from the active substance BAS 222 F if applied at l0x the maximum field rate of 2.80 kg a.i./hectare). Neither application rate had a significant effect on nitrogen transformation rates in the soil relative to the study control over 28 days as judged by measurement of of nitrate concentrations using a nitrate electrode.
5.2.1	NOEC	5.6 mg BF 222-EU/kg dry soil
5.2.2	EC_{10}	Not applicable
5.2.3	EC_{50}	Not applicable
5.3	**Conclusion**	BF 222-EU applied at rates anticipated as arising from application of lx and l0x the maximum application rates of the a.i. BAS 222 F had no significant effect on nitrogen transformation in Lucerne-amended soil.
5.3.1	Reliability	1
5.3.2	Deficiencies	No

Section A7.5.1.1(4) Inhibition to microbial activity (terrestrial)

Annex Point IIA7.4 **Effect of BF 222-EU on Nitrogen Transformation of the Soil Microflora**

IUCLID 4.4/05

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*Give month and year of evaluation or comments*
Materials and Methods	*State if the applicant's version is acceptable or indicate relevant discrepancies referring to the (sub) heading numbers and to applicant's summary and conclusion.*
Results and discussion	*Adopt applicant's version or include revised version. If necessary, discuss relevant deviations from applicant's view referring to the (sub)heading numbers*
Conclusion	*Adopt applicant's version or include revised version*
Reliability	*Based on the assessment of materials and methods include appropriate reliability indicator*
Acceptability	acceptable / not acceptable *(give reasons if necessary, e.g. if a study is considered acceptable despite a poor reliability indicator. Discuss the relevance of deficiencies and indicate if repeat is necessary.)*
Remarks	
	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	

Table A7_5_1_1-1: Microbial sample / Inoculum (*if applicable; include separate table for different samples*)

<table>
<tr><th>Criteria</th><th>Details</th></tr>
<tr><td>Nature</td><td>Soil sample</td></tr>
<tr><td>Sampling site:</td><td>Not stated</td></tr>
<tr><td>Geographical reference on the sampling site</td><td>Not stated</td></tr>
<tr><td>Data on the history of the site</td><td>Site not treated with plant protection products or fertilizers</td></tr>
<tr><td>Use pattern</td><td>Agricultural soil</td></tr>
<tr><td>Depth of sampling [cm]</td><td>Not stated</td></tr>
<tr><td>Sand / Silt / Clay content [% dry weight]</td><td>Loamy Sand, composition detailed below:-
<table>
<tr><th colspan="2">Particle Size (%)</th></tr>
<tr><td>2000 to ≥ 630 µm</td><td>5.4</td></tr>
<tr><td>630 to ≥ 200 µm</td><td>43.0</td></tr>
<tr><td>200 to ≥ 63 µm</td><td>25.6</td></tr>
<tr><td>63 to ≥ 20 µm</td><td>10.3</td></tr>
<tr><td>20 to ≥ 6.3 µm</td><td>6.5</td></tr>
<tr><td>6.3 to ≥ 2 µm</td><td>4.1</td></tr>
<tr><td><2 µm</td><td>5.3</td></tr>
<tr><td>Soil Type (DIN 4220)</td><td>SI Loamy Sand Lehmiger Sand</td></tr>
</table></td></tr>
<tr><td>pH</td><td>pH 6.2</td></tr>
<tr><td>Organic carbon content [% dry weight]</td><td>0.93%</td></tr>
<tr><td>Nitrogen content [% dry weight]</td><td>0.07% (prior to addition of lucerne)</td></tr>
<tr><td>Cation exchange capacity [mmol/kg]</td><td>6.6 mval Ba/100g dry weight</td></tr>
<tr><td>Initial microbial biomass</td><td>1.96% (Calculated from reported data)</td></tr>
<tr><td>Reference of methods</td><td>Pipette Method</td></tr>
<tr><td>Collection / storage of samples</td><td>Following mixing, each soil treatment group was distributed into sufficient 1.5 L glass jars to allow 3 replicates at each time-point. 3 replicates of 57.2 g (corresponding to 50 g dry soil) from each group were used to generate the day 0 carbon transformation values. The remainder of the samples were then stored, loosely covered with lids, in a temperature controlled incubator at 20±2°C until sampling at 7, 14 and 28 days. Sampling and analysis were performed with 3 replicates of 57.2 g (corresponding to 50 g dry soil) from each group.</td></tr>
<tr><td>Preparation of inoculum for exposure</td><td>Not applicable</td></tr>
<tr><td>Pretreatment</td><td>Water was added to bring the moisture content of each soil group to 45% of it's maximum water holding capacity.
Control: 67.8 g water were added to and mixed with</td></tr>
</table>

	1648.4 g of soil. Treated: 57.8 g water plus 10 g water containing BF 222-EU were added to and mixed with 1648.4 g of soil.

Table A7_5_1_1-2: Test organism (*if applicable*)

Criteria	**Details**
Species	Not applicable
Strain	Not applicable
Source	Not applicable
Sampling site	Not applicable
Laboratory culture	Not applicable
Method of cultivation	Not applicable
Preparation of inoculum for exposure	Not applicable
Pretreatment	Not applicable
Initial cell concentration	Not applicable

Table A7_5_1_1-3: Test system

Criteria	**Details**
Culturing apparatus	1.5 L Glass jars
Number of vessels / concentration	At least 4 at each concentration
Aeration device	None specified
Measuring equipment	Expandable Ion Analyser EA 940, Orion Res., Cambridge Ammonia Electrode, model 95-12-00, Orion Res., Cambridge Nitrate electrode, model 93-07-00, Orion Res., Cambridge
Test performed in closed vessels	Jars loosely covered with lid to allow air exchange

Table A7_5_1_1-4: Application of test substance

Criteria	Details
Application procedure	0.56 mg/kg (1x): 21.0 mg of BF 222-EU were dissolved in 250 mL of distilled water. 10 mL of this solution were added to the soil as part of the calculated addition of water necessary to achieve 45% of the soil's maximum water holding capacity to give an application rate of 0.56 mg BF 222-EU/kg dry soil. 5.6 mg/kg (10x): 84.0 mg of BF 222-EU were dissolved in 100 mL of distilled water. 10 mL of this solution were added to the soil as part of the calculated addition of water necessary to achieve 45% of the soil's maximum water holding capacity to give an application rate of 5.6 mg BF 222-EU/kg dry soil.
Carrier	Distilled Water
Concentration of liquid carrier [% v/v]	Included in the quantity of water added to give a WHC of 45%
Liquid carrier control	Water was added to the control to give a WHC of 45%.
Other procedures	None stated

Table A7_5_1_1-5: Test conditions

Criteria	Details
Organic substrate	Lucerne meal (Li-hol) containing 35.1% organic carbon/3.1% nitrogen (dry weight) was used. 7.5 g Lucerne meal were added to 1.5 kg equivalents of dry weight soil, resulting in 0.5% meal in soil and 15.5mg N/100 g of dry weight soil.
Incubation temperature	20±2°C Individual measurements were not provided.
Soil moisture	No further adjustments to soil moisture content were made after the addition of water to give a WHC of 45% at the start of the study
Method of soil incubation	The soil samples were incubated individually in their glass jars.
Aeration	The jars were loosely covered by the lids to allow air exchange. No additional aeration was provided.

Table A7_5_1_1-6: Effects of BF 222-EU on Nitrogen Transformation in a Loamy Sand Soil over 28 Days

Variant	Days after applicaüon			
	0	7	14	28
Control*	21.2	5.74	3.40	2.26
0.56mg BF 222-EU/kg dry soil*	21.0	5.69	3.40	2.25
% deviation from control**	-0.94	-0.87	0	-0.44
5.6 mg BF 222-EU/kg dry soil*	21.4	6.17	3.59	2.31
% deviation from control**	+0.96	+7.49	+5.59	+2.21

*Values reported are the mean of 3 measurements and are given as mg NO_3-N/kg dry soil/day

$$^{**}\%\ \text{Deviation} = \frac{\text{Treated - untreated soil}}{\text{untreated soil}} \times 100$$

Table A7_5_1_1-7: Summary of Effects of BF 222-EU on Nitrogen Transformation in a Loamy Sand Soil after 28 Days

Soil	% Deviation from Control**	
	0.56 mg BF 222-EU/kg dry soil	5.6 mg BF 222-EU/kg dry soil
Loamy Sand	-0.44	+2.21

+ = stimulation; - = inhibition

$$^{**}\%\ \text{Deviation} = \frac{\text{Treated - untreated soil}}{\text{untreated soil}} \times 100$$

Section 7.5.1.1 **Annex Point IIA7.4**	**Inhibition to microbial activity**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [X] **Limited exposure** [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [ ] **Other justification** [ ]	
Detailed justification:	This test is required if the risk assessment for the terrestrial compartment, based on the equilibrium partitioning method, indicates a concern for the terrestrial compartment. As the risk assessment for Zineb conducted on the basis of the equilibrium partitioning method indicates no cause for concern, it is considered that there is no necessity to conduct this study.	
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	*Give date of action*	
Evaluation of applicant's justification	*Discuss applicant's justification and, if applicable, deviating view*	
Conclusion	*Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data*	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section 7.5.1.2 **Annex Point IIA7.4**	**Acute toxicity to earthworms or other soil non-target macro-organisms**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [X] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [ ]**	
Detailed justification:	This test is required if the risk assessment for the terrestrial compartment, based on the equilibrium partitioning method, indicates a concern for the terrestrial compartment. As the risk assessment for Zineb conducted on the basis of the equilibrium partitioning method indicates no cause for concern, it is considered that there is no necessity to conduct this study.	
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	*Give date of action*	
Evaluation of applicant's justification	*Discuss applicant's justification and, if applicable, deviating view*	
Conclusion	*Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data*	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section A7.5.1.2(1)
Annex Point IIIA XIII 3.2
IUCLID 4.6.3/01

Earthworm, acute toxicity test

Effect of Metabolite ETU on the Mortality of the Earthworm *Eisenia Foetida*

Official use only

1 REFERENCE

1.1	**Reference**	Staab, F., (2001a) Effect of Metabolite ETU on the Mortality of the Earthworm *Eisenia Foetida,* BASF Aktiengesellschaft, BASF Agricultural Centre Limburgerhof, Crop Protection Division, Ecology and Environmental Analytics, P.O. Box 120, 67114 Limburgerhof, Germany, Report No. 96317, 17 January 2001.
1.2	**Data protection**	Yes
1.2.1	Data owner	BASF
1.2.2		
1.2.3	Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I

2 GUIDELINES AND QUALITY ASSURANCE

2.1	**Guideline study**	Yes OECD-Guideline 207. Earthworm, Acute Toxicity Tests: Artificial Soil Test.
2.2	**GLP**	Yes
2.3	**Deviations**	No

3 METHOD

3.1	**Test material**	BF 222-ETU
3.1.1	Lot/Batch number	01743-165 (PCP06001)
3.1.2	Specification	Deviating from specification given in section 2 as follows:- The test substance is a metabolite of BAS 222 F
3.1.3	Purity	99.9%
3.1.4	Composition of Product	Not applicable
3.1.5	Further relevant properties	None reported.
3.1.6	Method of analysis	Not applicable
3.2	**Reference substance**	No concurrent test with reference substance was performed
3.2.1	Method of analysis for reference substance	Not applicable
3.3	**Testing procedure**	*Non-entry field*
3.3.1	Preparation of the test substance	The test substance was suspended in acetone as detailed in table A7_5_1_2-1
3.3.2	Application of the test substance	The test substance in acetone was poured on to the soil. The acetone was evaporated, water was added to 35.8% (w/w) and the soil sample

		was thoroughly mixed.
3.3.3	Test organisms	*Eisenia foetida* as detailed in table A7_5_1_2-2
3.3.4	Test system	The test examined effects of a range of concentration of test substance on the mortality and biomass of worms in artificial soil (see table A7_5_1_2-3)
3.3.5	Test conditions	Incubation under constant illumination at 20-21°C with 34.8% moisture content at the start of the study (see table A7_5_1_2-4)
3.3.6	Test duration	14 days
3.3.7	Test parameter	Mortality, worm biomass, changes in behaviour and pathological symptoms
3.3.8	Examination	Test parameters were assessed after exposure for 7 days (except for weight) and 14 days
3.3.9	Monitoring of test substance concentration	No
3.3.10	Statistics	Due to the low mortality observed in the study, no statistical calculations to determine the LC_{50} were possible. The Dunnett test was applied to determine the NOAEC using Toxstat software (v3.5)
		4 RESULTS
4.1	**Filter paper test**	Not performed
4.1.1	Concentration	Not applicable
4.1.2	Number/ percentage of animals showing adverse effects	Not applicable
4.1.3	Nature of adverse effects	Not applicable
4.2	**Soil test**	
4.2.1	Initial concentrations of test substance	0 (control), 197.5, 296.3, 444.4, 666.7 and 1000 mg/kg dry weight artificial soil
4.2.2	Effect data (Mortality)	No mortality data above 10% was recorded in any of the study groups (see table A7_5_1_2-5). No LC_0, LC_{50} and LC_{100} values after test termination could be reported in table A7_5_1_2-6
4.2.3	Concentration / effect curve	The absence of concentration associated mortality obviates the need for a concentration-mortality curve at test termination
4.2.4	Other effects	Reduction in worm biomass was reported in the control and lowest concentration tested. Higher concentrations of up to 1000 mg/kg soil dry weight showed an increase in worm biomass (see table A7_5_1_2-8). No other behavioural or morphological changes were observed.
4.3	**Results of controls**	

Section A7.5.1.2(1) **Earthworm, acute toxicity test**
Annex Point IIIA XIII 3.2
IUCLID 4.6.3/01 **Effect of Metabolite ETU on the Mortality of the Earthworm *Eisenia Foetida***

4.3.1	Mortality	Mortality in the control group was 0% after 7 days and 2.5% after 14 days
4.3.2	Number/ percentage of earthworms showing adverse effects	The control consisted of 4 sets of 10. Mortality was confined to 1 worm in 1 set, corresponding to an overall figure of 2.5%
4.3.3	Nature of adverse effects	The only adverse effect assessed was mortality
4.4	**Test with reference substance**	No concurrent test with reference substance was performed
4.4.1	Concentrations	Not applicable
4.4.2	Results	Not applicable

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	The study followed OECD-Guideline 207 (Earthworm, Acute Toxicity Tests: Artificial Soil Test). The effects of BF 222-ETU on earthworms mortality and biomass in artificial soil containing a range of concentration of the test substance were investigated. 4 cultures of worms, each containing 10 worms, was set up at each of the 6 concentrations (including 0) tested. Mortality was assessed by counting viable worms after 7 and 14 days incubation. Biomass was assessed by weighing worms at the start and end of the study and expressing the % difference in mean biomass at each concentration.
5.2	**Results and discussion**	BF 222-ETU caused no distinct treatment related mortality in earthworms up to 1000 mg/kg soil dry weight, the highest concentration tested. Reduction in worm biomass was reported in the control and lowest concentration tested. Higher concentrations of up to 1000 mg/kg soil dry weight showed an increase in worm biomass. No other behavioural or morphological changes were observed.
5.2.1	LC_0	Not applicable
5.2.2	LC_{50}	>1000 mg/kg soil dry weight
5.2.3	LC_{100}	>1000 mg/kg soil dry weight
5.3	**Conclusion**	BF 222-ETU caused no distinct treatment related effects on mortality and had no adverse effects on Biomass of *Eisenia foetida* earthworms at concentrations of up to 1000 mg/kg soil dry weight. The validity criteria for the control group were fulfilled.
5.3.1	Other Conclusions	None
5.3.2	Reliability	1
5.3.3	Deficiencies	No

Section A7.5.1.2(1) **Earthworm, acute toxicity test**
Annex Point IIIA XIII 3.2
IUCLID 4.6.3/01 **Effect of Metabolite ETU on the Mortality of the Earthworm** *Eisenia Foetida*

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*Give date of action*
Materials and Methods	*State if the applicant's version is acceptable or indicate relevant discrepancies referring to the (sub) heading numbers and to applicant's summary and conclusion.*
Results and discussion	*Adopt applicant's version or include revised version. If necessary, discuss relevant deviations from applicant's view referring to the (sub)heading numbers*
Conclusion	LC_0: LC_{50}: LC_{100}: *Other conclusions:* *(Adopt applicant's version or include revised version)*
Reliability	*Based on the assessment of materials and methods include appropriate reliability indicator*
Acceptability	acceptable / non acceptable *(give reasons if necessary, e.g. if a study is considered acceptable despite a poor reliability indicator; if unacceptable, give reasons for unacceptability of study; discuss the relevance of the deficiencies. Indicate if repeat is necessary)*
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	

Table A7_5_1_2-1: Preparation of TS solution

Criteria	Details
Type and source of dilution water	Not applicable
Alkalinity / Salinity	Not applicable
Hardness	Not applicable
pH	Not applicable
Oxygen content	Not applicable
Conductance	Not applicable
Holding water different from dilution water	Not reported
In case of the use of an organic solvent	
Dispersion	Not reported
Vehicle	Yes, acetone was used to suspend the test substance
Concentration of vehicle	100%
Vehicle control performed	Not stated
Other procedures	None described

Table A7_5_1_2-2: Test organisms

Criteria	Details
Species/strain	*Eisenia foetida*
Source of the initial stock	BASF's own culture
Culturing techniques	Kept in boxes and fed with horse manure
Age/weight	< 1 year old/250-600 mg body weight
Pre-treatment	None reported

Table A7_5_1_2-3: Test system

Criteria	Details
Artificial soil test substrate	20% Kaolin clay 69% Quartz sand 10% Sphagnum peat 1% CaCO3 The dry constituents were blended and mixed thoroughly with some water using a Krups 3-mix. Following the determination of water holding capacity, water was added to achieve a soil humidity of *ca* 60% of maximum water holding capacity. The artificial soil was determined to be of pH 5.8 Total Carbon and Total Organic Carbon content were not reported.
Test mixture	See nominal test concentrations below.
Size, volume and material of test container	1.0 L Glass jars with glass lids
Amount of artificial soil (kg)/ container	0.75 kg wet weight/container
Nominal levels of test concentrations	0 (control), 197.5, 296.3, 444.4, 666.7 and 1000 mg/kg dry weight artificial soil
Number of replicates/concentration	4
Number of earthworms/test concentration	40
Number of earthworms/container	10
Light source	Yes, type of source not stated
Test performed in closed vessels due to significant volatility of test substrate	Not stated

Table A7_5_1_2-4: Test conditions

Criteria	Details
Test temperature	The tests were conducted in an incubator set at 20-21°C
Moisture content	Start of Study: 34.8 g water/100 g soil dry weight (corresponding to *ca* 60%maximum WHC) End of study: 34.8 g water/100 g soil dry weight (mean of triplicate measurements)
pH	pH 5.8
Adjustment of pH	None stated
Light intensity / photoperiod	Continuous illumination, intensity not stated
Relevant degradation products	None stated

Table A7_5_1_2-5: Mortality data

Test Substance Concentration (nominal) [mg/kg artificial soil]	**Mortality**			
	Number		**Percentage**	
	7 d	**14 d**	**7 d**	**14 d**
0 (Control)	0	1	0	2.5
197.5	0	0	0	0
296.3	3	4	7.5	10
444.4	1	1	2.5	2.5
666.7	0	0	0	0
1000	0	1	0	2.5
Temperature [°C]	20-21°C	20-21°C		
pH	Not reported	Not reported		
Moisture content	Not reported	34.8%		

Table A7_5_1_2-6: Effect data

	14 d [mg/kg soil][1]	**95 % c.l.**
LC_0	>1000	Not applicable
LC_{50}	>1000	Not applicable
LC_{100}	>1000	Not applicable

[1] based on nominal concentrations

Table A7_5_1_2-7: Validity criteria for acute earthworm test according to OECD 207

	fulfilled	**Not fulfilled**
Mortality of control animals < 10%	**X**	

Table A7_5_1_2-8: Relative Change in Mean Biomass

Test Substance Concentration (nominal) [mg/kg artificial soil]	Relative Change (%)
0 (Control)	-8.96
197.5	-3.98
296.3	+1.77
444.4	+1.64
666.7	+7.44
1000	+4.15

Calculated after 14 days relative to starting biomass

Section A7.5.1.2(2) Earthworm, acute toxicity test

Annex Point IIIA XIII 3.2

IUCLID 4.6.3/02

Effect of BF 222-EU on the Mortality of the Earthworm *Eisenia Foetida*

Official use only

		1 REFERENCE
1.1	**Reference**	Staab, F., (2001b) Effect of BF 222-EU on the Mortality of the Earthworm *Eisenia Foetida,* BASF Aktiengesellschaft, BASF Agricultural Centre Limburgerhof, Crop Protection Division, Ecology and Environmental Analytics, P.O. Box 120, 67114 Limburgerhof, Germany, Report No. 99457, 17 January 2001.
1.2	**Data protection**	Yes
1.2.1	Data owner	BASF
1.2.2		
1.2.3	Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I
		2 GUIDELINES AND QUALITY ASSURANCE
2.1	**Guideline study**	Yes OECD-Guideline 207. Earthworm, Acute Toxicity Tests: Artificial Soil Test.
2.2	**GLP**	Yes
2.3	**Deviations**	No
		3 METHOD
3.1	**Test material**	BF 222-EU
3.1.1	Lot/Batch number	01743-161 (PCP05998)
3.1.2	Specification	Deviating from specification given in section 2 as follows:- The test substance is a metabolite of BAS 222 F
3.1.3	Purity	88.6%
3.1.4	Composition of Product	Not applicable
3.1.5	Further relevant properties	None reported.
3.1.6	Method of analysis	Not applicable
3.2	**Reference substance**	No concurrent test with reference substance was performed
3.2.1	Method of analysis for reference substance	Not applicable
3.3	**Testing procedure**	
3.3.1	Preparation of the test substance	The test substance was suspended in water as detailed in table A7_5_1_2-1
3.3.2	Application of the test substance	The test substance in water was poured on to the soil and thoroughly mixed.

Section A7.5.1.2(2) **Earthworm, acute toxicity test**
Annex Point IIIA XIII 3.2
IUCLID 4.6.3/02 **Effect of BF 222-EU on the Mortality of the Earthworm *Eisenia Foetida***

3.3.3	Test organisms	*Eisenia foetida* as detailed in table A7_5_1_2-2
3.3.4	Test system	The test examined effects of a range of concentration of test substance on the mortality and biomass of worms in artificial soil (see table A7_5_1_2-3)
3.3.5	Test conditions	Incubation under constant illumination at 20-21°C with 34.8% moisture content at the start of the study (see table A7_5_1_2-4)
3.3.6	Test duration	14 days
3.3.7	Test parameter	Mortality, worm biomass, changes in behaviour and pathological symptoms
3.3.8	Examination	Test parameters were assessed after exposure for 7 days (except for weight) and 14 days
3.3.9	Monitoring of test substance concentration	No
3.3.10	Statistics	Due to the low mortality observed in the study, no statistical calculations to determine the LC_{50} were possible. The Dunnett test was applied to determine the NOAEC using Toxstat software (v3.5)
		4 RESULTS
4.1	**Filter paper test**	Not performed
4.1.1	Concentration	Not applicable
4.1.2	Number/ percentage of animals showing adverse effects	Not applicable
4.1.3	Nature of adverse effects	Not applicable
4.2	**Soil test**	
4.2.1	Initial concentrations of test substance	0 (control), 175.0, 262.5, 393.7, 590.7 and 886.0 mg (corrected for purity)/kg dry weight artificial soil, corresponding to concentrations of 0 (control), 197.5, 296.3, 444.4, 666.7 and 1000 mg/kg dry weight artificial soil before correction.
4.2.2	Effect data (Mortality)	No mortalities were recorded in any of the study groups (see table A7_5_1_2-5). No LC_0, LC_{50} and LC_{100} values after test termination could be reported in table A7_5_1_2-6
4.2.3	Concentration / effect curve	The absence of mortality obviates the need for a concentration-mortality curve at test termination
4.2.4	Other effects	No reduction in worm biomass was reported in the control or at any concentration tested. The worm biomass increased at all concentrations tested up to 886.0 mg (corrected for purity)/kg soil dry weight , especially in the 3 highest treatments (see table A7_5_1_2-8). No other behavioural or morphological changes were observed.

Section A7.5.1.2(2) **Earthworm, acute toxicity test**
Annex Point IIIA XIII 3.2
IUCLID 4.6.3/02 **Effect of BF 222-EU on the Mortality of the Earthworm *Eisenia Foetida***

4.3	**Results of controls**	
4.3.1	Mortality	Mortality in the control group was 0% after 7 and 14 days
4.3.2	Number/ percentage of earthworms showing adverse effects	The control consisted of 4 sets of 10. There were no mortalities in any of the 4 sets of control worms.
4.3.3	Nature of adverse effects	No adverse effects were noted.
4.4	**Test with reference substance**	No concurrent test with reference substance was performed
4.4.1	Concentrations	Not applicable
4.4.2	Results	Not applicable

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	The study followed OECD-Guideline 207 (Earthworm, Acute Toxicity Tests: Artificial Soil Test). The effects of BF 222-EU on earthworms mortality and biomass in artificial soil containing a range of concentration of the test substance were investigated. 4 cultures of worms, each containing 10 worms, was set up at each of the 6 concentrations (including 0) tested. Mortality was assessed by counting viable worms after 7 and 14 days incubation. Biomass was assessed by weighing worms at the start and end of the study and expressing the % difference in mean biomass at each concentration.
5.2	**Results and discussion**	BF 222-EU caused no mortality in earthworms up to the highest concentrations tested of nominal 1000 mg/kg soil dry weight, (equivalent to 886 mg/kg soil dry weight after correcting for purity). The worm biomass increased at all concentrations tested, especially in the 3 highest treatment groups. No other behavioural or morphological changes were observed.
5.2.1	LC_0	>886 mg (after correcting for purity)/kg soil dry weight corresponding to 1000 mg/kg soil dry weight before correction for purity.
5.2.2	LC_{50}	>886 mg (after correcting for purity)/kg soil dry weight corresponding to 1000 mg/kg soil dry weight before correction for purity.
5.2.3	LC_{100}	>886 mg (after correcting for purity)/kg soil dry weight corresponding to 1000 mg/kg soil dry weight before correction for purity.
5.3	**Conclusion**	BF 222-EU caused no distinct treatment related effects on mortality and had no adverse effects on Biomass of *Eisenia foetida* earthworms at nominal concentrations of up to 1000 mg/kg soil dry weight (equivalent to 886 mg/kg soil dry weight after correcting for purity). The validity criteria for the control group were fulfilled.
5.3.1	Other Conclusions	None
5.3.2	Reliability	1
5.3.3	Deficiencies	No

Section A7.5.1.2(2)
Annex Point IIIA XIII 3.2
IUCLID 4.6.3/02

Earthworm, acute toxicity test

Effect of BF 222-EU on the Mortality of the Earthworm *Eisenia Foetida*

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*Give date of action*
Materials and Methods	*State if the applicant's version is acceptable or indicate relevant discrepancies referring to the (sub) heading numbers and to applicant's summary and conclusion.*
Results and discussion	*Adopt applicant's version or include revised version. If necessary, discuss relevant deviations from applicant's view referring to the (sub)heading numbers*
Conclusion	LC_0: LC_{50}: LC_{100}: *Other conclusions:* *(Adopt applicant's version or include revised version)*
Reliability	*Based on the assessment of materials and methods include appropriate reliability indicator*
Acceptability	acceptable / non acceptable *(give reasons if necessary, e.g. if a study is considered acceptable despite a poor reliability indicator; if unacceptable, give reasons for unacceptability of study; discuss the relevance of the deficiencies. Indicate if repeat is necessary)*
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	

Table A7_5_1_2-1: Preparation of TS solution

Criteria	Details
Type and source of dilution water	Not reported
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	Not applicable
Vehicle	Not applicable
Concentration of vehicle	Not applicable
Vehicle control performed	Not applicable
Other procedures	Not applicable

Table A7_5_1_2-2: Test organisms

Criteria	Details
Species/strain	*Eisenia foetida*
Source of the initial stock	BASF's own culture
Culturing techniques	Kept in boxes and fed with horse manure
Age/weight	< 1 year old/250-600 mg body weight
Pre-treatment	None reported

Table A7_5_1_2-3: Test system

Criteria	Details
Artificial soil test substrate	20% Kaolin clay 69% Quartz sand 10% Sphagnum peat 1% CaCO3 The dry constituents were blended and mixed thoroughly with some water using a Krups 3-mix. Following the determination of water holding capacity, water was added to achieve a soil humidity of *ca* 60% of maximum water holding capacity. The artificial soil was determined to be of pH 5.8 Total Carbon and Total Organic Carbon content were not reported.
Test mixture	See nominal test concentrations below.
Size, volume and material of test container	1.0 L Glass jars with glass lids
Amount of artificial soil (kg)/ container	0.75 kg wet weight/container
Nominal levels of test concentrations	0 (control), 197.5, 296.3, 444.4, 666.7 and 1000 mg/kg dry weight artificial soil
Number of replicates/concentration	4
Number of earthworms/test concentration	40
Number of earthworms/container	10
Light source	Yes, type of source not stated
Test performed in closed vessels due to significant volatility of test substrate	Not stated

Table A7_5_1_2-4: Test conditions

Criteria	Details
Test temperature	The tests were conducted in an incubator set at 20-21°C
Moisture content	Start of Study: 34.8 g water/100 g soil dry weight (corresponding to *ca* 60%maximum WHC) End of study: 32.5 g water/100 g soil dry weight (mean of triplicate measurements)
pH	pH 5.8
Adjustment of pH	None stated
Light intensity / photoperiod	Continuous illumination, intensity not stated
Relevant degradation products	None stated

Table A7_5_1_2-5: Mortality data

Test Substance Concentration (nominal) [mg/kg artificial soil]	Test Substance Concentration (corrected for purity) [mg/kg artificial soil]	Mortality			
		Number		Percentage	
		7 d	14 d	7 d	14 d
0 (Control)	0 (Control)	0	0	0	0
197.5	175.0	0	0	0	0
296.3	262.5	0	0	0	0
444.4	393.7	0	0	0	0
666.7	590.7	0	0	0	0
1000	886.0	0	0	0	0
Temperature [°C]		20-21°C	20-21°C		
pH		Not reported	Not reported		
Moisture content		Not reported	32.5%		

Table A7_5_1_2-6: Effect data

	14 d [mg/kg soil][1]	95 % c.l.
LC_0	>886	Not applicable
LC_{50}	>886	Not applicable
LC_{100}	>886	Not applicable

[1] based on nominal concentrations corrected for purity

Table A7_5_1_2-7: Validity criteria for acute earthworm test according to OECD 207

	fulfilled	Not fulfilled
Mortality of control animals < 10%	X	

Table A7_5_1_2-8: Relative Change in Mean Biomass based on Nominal Concentrations

Test Substance Concentration (nominal) [mg/kg artificial soil]	Test Substance Concentration (corrected for purity) [mg/kg artificial soil]	Relative Change (%)
0 (Control)	0 (Control)	+0.71
197.5	175.0	+4.01
296.3	262.5	+5.85
444.4	393.7	+10.86
666.7	590.7	+10.01
1000	886.0	+10.58

Calculated after 14 days relative to starting biomass

Section A7.5.1.3	Acute toxicity to plants	
Annex Point IIA VII		
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	Technically not feasible [ ] Scientifically unjustified [X]	
Limited exposure [ ]	Other justification [ ]	
Detailed justification:	The available terrestrial toxicity testing is considered to be adequate for the assessment of the overall risk posed by the proposed use of Zineb to terrestrial organisms. Furthermore, the potential for exposure of plants to Zineb as a result of the proposed use is considered to be minimal. In view of the above, and given that acute toxicity testing in plants is not identified as either a core or a product type-specific data requirement for active ingredients in product type 21, it is concluded that there is no requirement for testing of this type.	
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	*Give date of action*	
Evaluation of applicant's justification	*Discuss applicant's justification and, if applicable, deviating view*	
Conclusion	*Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data*	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section A7.5.2.1 Annex Point IIIA XIII.3.2	Reproduction study with 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 [X]** **Other justification [ ]**	
Detailed justification:	This test is required if the risk assessment for the terrestrial compartment indicates that there is cause for concern. As the risk assessment conducted on the basis of equilibrium partitioning indicates that there is no cause for concern, it is considered to be unnecessary to conduct this test.	
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	*Give date of action*	
Evaluation of applicant's justification	*Discuss applicant's justification and, if applicable, deviating view*	
Conclusion	*Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data*	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section A7.5.2.2	Long-term tests with terrestrial plants	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [X]	
Limited exposure [ ]	**Other justification** [ ]	
Detailed justification:	The available terrestrial toxicity testing is considered to be adequate for the assessment of the overall risk posed by the proposed use of zineb to terrestrial organisms. Furthermore, the potential for exposure of plants to zineb as a result of the proposed use is considered to be minimal. In view of the above, and given that long-term toxicity testing in plants is not identified as either a core or a product type-specific data requirement for active ingredients in product type 21, it is concluded that there is no requirement for testing of this type.	
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	*Give date of action*	
Evaluation of applicant's justification	*Discuss applicant's justification and, if applicable, deviating view*	
Conclusion	*Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data*	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section A7.5.3.1.1 **Annex Point IIIA, XIII.1.1**	**Acute oral toxicity**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [X]** **Other justification [ ]**	
Detailed justification:	The potential for exposure of birds to Zineb as a direct result of the proposed use is considered to be minimal. Furthermore, available data on the potential for bioaccumulation of Zineb and its metabolites indicate that there is no significant potential for secondary poisoning to result in fish-eating birds. In view of the above, and given that acute toxicity testing in birds is not identified as either a core or a product type-specific data requirement for active ingredients in product type 21, it is concluded that there is no requirement for testing of this type.	
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	*Give date of action*	
Evaluation of applicant's justification	*Discuss applicant's justification and, if applicable, deviating view*	
Conclusion	*Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data*	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section A7.5.3.1.2 **Annex Point IIIA, XIII.1.2**	**Short-term toxicity**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [X]** **Other justification [ ]**	
Detailed justification:	The potential for exposure of birds to Zineb as a direct result of the proposed use is considered to be minimal. Furthermore, available data on the potential for bioaccumulation of Zineb and its metabolites indicate that there is no significant potential for secondary poisoning to result in fish-eating birds. In view of the above, and given that short-term toxicity testing in birds is not identified as either a core or a product type-specific data requirement for active ingredients in product type 21, it is concluded that there is no requirement for testing of this type.	
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	*Give date of action*	
Evaluation of applicant's justification	*Discuss applicant's justification and, if applicable, deviating view*	
Conclusion	*Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data*	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section A7.5.3.1.3 Annex Point IIIA, XIII.1.3	Effects on reproduction	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure** [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [X] **Other justification** [ ]	
Detailed justification:	The potential for exposure of birds to Zineb as a direct result of the proposed use is considered to be minimal. Furthermore, available data on the potential for bioaccumulation of Zineb and its metabolites indicate that there is no significant potential for secondary poisoning to result in fish-eating birds. In view of the above, and given that effects on reproduction testing in birds is not identified as either a core or a product type-specific data requirement for active ingredients in product type 21, it is concluded that there is no requirement for testing of this type.	
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	*Give date of action*	
Evaluation of applicant's justification	*Discuss applicant's justification and, if applicable, deviating view*	
Conclusion	*Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data*	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section A7.5.4.1 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** [X] **Other justification** [ ]	
Detailed justification:	At least one test and bees and one on another beneficial arthropod may be generally required for insecticides, acaricides and substances in products used to control other arthropods which are used outdoors (product type 18). Such tests are not usually needed for other product types. As Zineb is to be used in product type 21 and there is no potential for significant exposure to occur as a result of the proposed use, it is concluded that there is no requirement for testing of this type.	
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	*Give date of action*	
Evaluation of applicant's justification	*Discuss applicant's justification and, if applicable, deviating view*	
Conclusion	*Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data*	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
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 [X] **Limited exposure** [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [ ] **Other justification** [ ]	
Detailed justification:	A theoretical terrestrial bioconcentration factor (BCF) of 0.865 has been calculated for Zineb using the EUSES 2.0.3 computer programme, suggesting that Zineb will not be subject to bioaccumulation. This conclusion is consistent with the results of a BCF study conducted in fish (refer to TNG summary A7.4.3.3.1).	
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	*Give date of action*	
Evaluation of applicant's justification	*Discuss applicant's justification and, if applicable, deviating view*	
Conclusion	*Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data*	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
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 [X]** **Other justification [ ]**	
Detailed justification:	There is no requirement to perform further tests as the active substance exposure assessment does not suggest that secondary poisoning is a concern for predators (refer to Document IIB).	
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	*Give date of action*	
Evaluation of applicant's justification	*Discuss applicant's justification and, if applicable, deviating view*	
Conclusion	*Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data*	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
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 [X]** **Other justification [ ]**	
Detailed justification:	There is no requirement to perform these tests as there is no indication from either the exposure assessment or the proposed use pattern that the active ingredient result in exposure of other non-target terrestrial organisms at levels that are likely to result in long-term adverse effects.	
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	*Give date of action*	
Evaluation of applicant's justification	*Discuss applicant's justification and, if applicable, deviating view*	
Conclusion	*Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data*	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section 7.5.7.1.1 **Annex Point IIIA, XIII.3.4**	**Acute oral toxicity**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [X]** **Other justification [ ]**	
Detailed justification:	There is no requirement to perform further tests on mammals as there should be no significant exposure based on the proposed use of the active ingredient. Available information on the acute oral toxicity of zineb in mammals is summarised in TNG Section IIIA 6.1.1.	
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	*Give date of action*	
Evaluation of applicant's justification	*Discuss applicant's justification and, if applicable, deviating view*	
Conclusion	*Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data*	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section 7.5.7.1.2 **Annex Point IIIA, XIII.3.4**	**Short term toxicity**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [X]** **Other justification [ ]**	
Detailed justification:	There is no requirement to perform further tests on mammals as there should be no significant exposure based on the proposed use of the active ingredient. Available information on the short term toxicity of zineb in mammals is summarised in TNG Section IIIA 6.3.	
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	*Give date of action*	
Evaluation of applicant's justification	*Discuss applicant's justification and, if applicable, deviating view*	
Conclusion	*Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data*	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section 7.5.7.1.3 **Annex Point IIIA, XIII.3.4**	**Effects on reproduction**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [X]** **Other justification [ ]**	
Detailed justification:	There is no requirement to perform further tests on mammals as there should be no significant exposure based on the proposed use of the active ingredient. Available information on the effects on reproduction of zineb in mammals is summarised in TNG Section IIIA 6.8.	
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	*Give date of action*	
Evaluation of applicant's justification	*Discuss applicant's justification and, if applicable, deviating view*	
Conclusion	*Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data*	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section 7.6 Annex Point IIA, IIIA, VII.7.8; XII.4; XIII.	Summary of ecotoxicological effects and fate and behaviour in the environment	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [ ]	
Limited exposure [ ]	**Other justification** [X]	
Detailed justification:	The ecotoxicological effects, and fate and behaviour in the environment, are summarised in Document IIA.	
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	*Give date of action*	
Evaluation of applicant's justification	*Discuss applicant's justification and, if applicable, deviating view*	
Conclusion	*Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data*	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section A8 Measures necessary to protect man, animals and the environment

Subsection (Annex Point)			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**	The following precautions are recommended on the safety data sheet: Technical protective measures: Provide appropriate exhaust and ventilation at machinery and at places where dust can be generated. Provide showers and eye baths. Handling: Avoid producing or diffusing dust into the air. Personal protection: Respiratory protection - wear a suitable anti-dust mask. Skin protection – wear suitable protective clothing and gloves. Eye protection – wear eye and face protection. Exposure limits: Mean exposure limit value of dusts = 10 mg/m^3. Mean exposure limit value of alveolar dusts = 5 mg/m^3.	
8.1.1	**Methods and precautions concerning production, handling and use of the active substance and its formulations**	• *engineering controls, e.g. LEV, contained use, closed system* Active substance: Provide appropriate exhaust and ventilation at machinery and at places where dust can be generated. Exposure limits for zineb: Mean exposure limit value of dusts = 10 mg/m^3. Mean exposure limit value of alveolar dusts = 5 mg/m^3. Formulated products: Provide adequate ventilation. Where reasonably practicable, this should be achieved by the use of local exhaust ventilation and good general extraction. • *hygiene measures like segregation of working areas, barriers against splashes* Active substance: When using, do not eat, drink or smoke. Change clothes when they become contaminated. Formulated products: Smoking, eating and drinking should be prohibited in all preparation and application areas. Handle containers carefully to prevent damage and spillage.	

Section A8 Measures necessary to protect man, animals and the environment

Official use only

Prevent unauthorised access.

- *protective gloves (tested by a certified institution, protection factor), respiratory protective equipment (type and where applicable dependent on the level of exposure), further PPE if necessary (work clothing)*

Active substance:

Respiratory protection: Wear a suitable anti-dust mask.
Hand protection: Wear suitable protective gloves.
Skin protection: Wear suitable protective clothing.
Eye protection: Wear eye and face protection.

Formulated products:

Professional use:
Respiratory protection: Workers exposed to concentrations above the exposure limit must use the appropriate, certified respirators. When spraying the product, use a respiratory mask with charcoal and dust filters (as filter combination A2-P2). In confined spaces use compressed air or fresh air respiratory equipment.
Hand protection: Nitrile rubber gloves should be worn during mixing and application.
Skin protection: Overalls which cover the body, arms and legs must be worn. Skin should not be exposed.
Eye protection: Wear safety eyewear, e.g. safety spectacles, goggles or visors to protect against the splash of liquids. Eyewear should comply with BS 2092.

Non-professional use:
A long sleeve, long leg cotton overall.
Boots or similar (i.e. not open toed footwear).
Suitable eye protection

- *the protection of bystanders, the protection in case of secondary exposure*

Active substance:

Production and use of the active substance will be carried out under controlled conditions that will ensure segregation of bystanders and thereby prevent secondary exposure.

Formulated products:

Protection of bystanders and the prevention of secondary exposure is achieved by the creation of an exclusion zone around the vessel during the application of the formulated product. No significant secondary exposure will occur once the paint is surface dry.

Section A8 Measures necessary to protect man, animals and the environment

Official use only

- *precautionary measures against environmental exposure, e.g. appropriate use of control systems to avoid contamination of the surrounding environment, for example, via ventilation systems or drains*

Active substance:

Prevent any leakage.
Do not allow spilled material to be released into sewers or natural waters.

Formulated products:

Contain and absorb any spillage with non-combustible materials e.g. sand, earth, vermiculite. Place in closed containers for disposal.
Clean the area, preferably with a detergent.
Do not allow spills to enter drains or watercourses.

8.1.2 Methods and precautions concerning storage of the active substance and its formulations

Active substance:

Keep containers in a well ventilated place.
Keep material only in the original container.
Keep containers tightly closed.
Keep in a dry place.
Do not stack more than three pallets high.

Recommended packing material is a bag with a polyethylene inner liner of minimum 75 µm thickness.

Formulated products:

Store in a well ventilated, dry place away from sources of heat and direct sunlight.
Store on concrete or other impervious floor, preferably with bunding to contain any spillage.
Do not stack more than three pallets high.
Keep containers tightly closed and upright to prevent leakage.
Keep material in the original container or one of the same material.
Handle containers carefully to prevent damage and spillage.

8.1.3 Methods and precautions concerning transport of the active substance and its formulations

Active substance:

RID/ADR: Class 4.1
Packing group III
Label No. 4.1

Road Transport Description (ADR 2003): METAL SALTS OF ORGANIC COMPOUNDS, FLAMMABLE, N.O.S. (ZINEB), 4.1, UN3181, III.

IMO-IMDG: Class 4.1 (flammable solid)
Label No 4.1
Packing group: III

Transport description (IMDG): METAL SALTS OF ORGANIC COMPOUNDS, FLAMMABLE, N.O.S. (ZINEB), 4.1, UN3181, PG III.

Section A8 Measures necessary to protect man, animals and the environment

Official use only

Formulated products:

RID/ADR: UN1263 Paint, 3, III

IMDG: Class: 3
Proper shipping name: PAINT
UN No: 1263
Ems: F-E, S-E
Packaging group: III
Marine pollutant: No

ICAO/IATA: Shipping name: PAINT
Class: 3
UN No: 1263
Packaging group: III

8.1.4 Methods and precautions concerning fire of the active substance and its formulations

Active substance:

Suitable extinguishing media:
Foam, dry chemicals, carbon dioxide. Water should only be used in the event of a major fire.

Special exposure hazards:
Thermal decomposition may give rise to flammable and toxic products, including carbon disulphide, hydrogen sulphide, oxides of sulphur, oxides of nitrogen and oxides of carbon.

Protection for fire-fighters:
Use self-contained respiratory apparatus and protective clothes.

Formulated products:

Suitable extinguishing media:
Alcohol resistant foam, carbon dioxide, dry powder, water spray (do not use water jet).

Special exposure hazards:
Fire will produce dense black smoke. Decomposition products may be hazardous to health.

8.2 In case of fire, nature of reaction products, combustion gases, etc. (IIA8.2)

Zineb is classified as highly flammable (according to EU Test method A.10).

The following information is based on a knowledge of chemical composition and experience in use, not specific testing.

Active substance:

Thermal decomposition may give rise to flammable and toxic products, including carbon disulphide, hydrogen sulphide, oxides of sulphur, oxides of nitrogen and oxides of carbon.

Formulated products:

Fire will produce dense black smoke. Decomposition products may be hazardous to health.

Section A8 Measures necessary to protect man, animals and the environment

			Official use only
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**	First aid measures: Inhalation: Move to fresh air. Skin contact: Wash immediately and abundantly with soap and water. Eye contact: Wash immediately and abundantly with water. If irritation persists, consult a specialist. Ingestion: In case of problems consult a doctor. Information for doctors: Treat symptomatically. There is no specific antidote.	
8.3.2	**Emergency measures to protect the environment**	Environmental precautions: Prevent any further leakage. Do not allow spilled material to be released into sewers or natural waters. Methods for cleaning up: Recover the product by sweeping up or vacuuming without raising dust. Personal precautions: Evacuate non-essential staff and those not equipped with individual protection apparatus. Wear appropriate protective clothing and gloves. Wear a suitable anti-dust mask.	
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**	In view of the very low vapour pressure of the active substance, release into the air compartment is very unlikely. There is no possibility of decontamination or destruction.	
8.4.2	**Possibility of destruction or decontamination following release in water, including drinking water**	There are no recommended decontamination procedures. Contact with water should be avoided.	
8.4.3	**Possibility of destruction or decontamination following release in or on soil**	Contaminated soil should be collected and incinerated.	
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**	

Section A8 Measures necessary to protect man, animals and the environment

			Official use only
		incineration (IIA8.5) Disposal of waste: Eliminate the product in an approved collecting and treatment centre for chemical waste in accordance with local and national regulations. Disposal of packaging: Do not reuse, burn or litter the empty packaging. Eliminate the contaminated packaging in an approved collecting and recycling centre in accordance with local and national regulations.	
8.5.1	**Possibility of re-use or recycling**	The active substance cannot be recycled.	
8.5.2	**Possibility of neutralisation of effects**	No methods are available for neutralisation of effects.	
8.5.3	**Conditions for controlled discharge including leachate qualities on disposal**	Controlled discharge is not recommended.	
8.5.4	**Conditions for controlled incineration**	In accordance with local and national regulations the test substance must be incinerated in a suitable incineration plant holding a permit delivered by the competent authorities.	
8.6		**Observations on undesirable or unintended side-effects, e.g. on beneficial and other non-target organisms (IIA8.6)** There are no reported observations of undesirable or unintended side-effects on beneficial or other non-target organisms as a result of the use of Zineb as an active ingredient in antifouling paint. The rapid degradation of Zineb and its metabolites and its low octanol-water partition coefficient indicate that potential for bioaccumulation and bioconcentration is negligible. There is therefore no significant potential for secondary poisoning of carnivores. This conclusion is supported by the results of a bioconentration study in fish that indicated no significant potential.	
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)** Zineb is classed in List II of the Annex to Directive 80/68/EEC.	

Evaluation by Competent Authorities	
Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	

Section A8 Measures necessary to protect man, animals and the environment

	Official use only
Materials and methods **Results and discussion** **Conclusion** **Reliability** **Acceptability** **Remarks**	
Date **Results and discussion** **Conclusion** **Reliability** **Acceptability** **Remarks**	

Section A9 Classification and labelling

Annex Point IIA, IX

9.1 Current classification according to Directive 67/548/EEC	Classification	Xi	Irritant.	**Official use only**
	R phrases	R37 R43	Irritating to respiratory system. May cause sensitization by skin contact.	
	S phrases	S2 S8 S24/25 S46	Keep out of the reach of children. Keep container dry. Avoid contact with skin and eyes. If swallowed, seek medical advice. immediately and show this container or label.	
9.2 Proposed classification	Class of danger	N F	Dangerous for the environment. Highly flammable.	
	R phrases	R11 R50/53	Highly flammable. Very toxic to aquatic organisms. May cause long-term adverse effects in the aquatic environment.	
	S phrases	S8 S60	Keep container dry. This material and its container must be disposed of as hazardous waste.	

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*Give date of action*
Materials and Methods	*State if the applicants version is acceptable or indicate relevant discrepancies referring to the (sub) heading numbers and to applicant's summary and conclusion.*
Results and discussion	*Adopt applicant's version or include revised version. If necessary, discuss relevant deviations from applicant's view referring to the (sub)heading numbers*
Conclusion	*Other conclusions:* *(Adopt applicant's version or include revised version)*
Reliability	*Based on the assessment of materials and methods include appropriate reliability indicator*
Acceptability	*acceptable / not acceptable* *(give reasons if necessary, e.g. if a study is considered acceptable despite a poor reliability indicator. Discuss the relevance of deficiencies and indicate if repeat is necessary.)*
Remarks	
	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	

Section 10 **Annex Point IIB, X**	**SUMMARY AND EVALUATION OF SECTIONS 2 TO 9**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [X]**	
Detailed justification:	Refer to Document IIA for a summary and evaluation of the data presented in Sections 2 to 9.	
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	*Give date of action*	
Evaluation of applicant's justification	*Discuss applicant's justification and, if applicable, deviating view*	
Conclusion	*Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data*	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		