	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*02.06.2005*
Materials and Methods	Applicant version is not acceptable since the study summary are not presented according to the TNsG on Dossier Preparation under directive 98/8/EC. The study are presented according to the PPP Directive, Tier II.
Results and discussion	RMS accept applicant's version.
Conclusion	Applicant's version is acceptable. LOEC: 17 mg/kg NOEC: 8.4 mg/kg Other conclusions: AC 303,630 adversely affected survival of *Eisenia foetida* at 17,34 and 66 mg/kg concentrations in the artificial soil, but not at lower concentrations. Worms exposed to 17 mg/kg of AC 303,630 showed a statistically greater weight loss than (pooled) controls, but worms exposed at 4.0 and 8.4 mg/kg did not exhibit a statistically significant weight loss. Thus the LOEC for survival can be stated to be 17 mg/kg, while the NOEC for effects is 8.4 mg/kg.
Reliability	1
Acceptability	Acceptable
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	

91/414/EEC Annex	**II**	**Toxicity to Non-target Plants - Acute toxicity**
98/8/EC Annex	**IIIA XIII 3.4**	
PPPD Point addressed	**8.6**	
BPD Point addressed	**7.5.1.3**	

For Official Use Only

1.1	**Title**	Evaluation of CL 303630 (Chlorfenapyr) for Herbicidal Activity [redacted]
1.2	**Report Number**	[redacted]
1.3	**Lab Report No.**	[redacted]
1.4	**Cross Reference**	Not applicable
1.5	**Authors**	[redacted]
1.6	**Date of Report**	Undated. Testing was performed in 1989, 1991, and 1992.
1.7	**Published**	No.
1.8	**Data Protection and Owner**	Yes; [redacted]
1.9	**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 / authorization].
2.1	**Testing Facility**	[redacted]
2.2	**Dates of Experimental Work**	Testing was performed in 1989, 1991, and 1992.
3	**Objectives**	The purpose of this test was to evaluate the potential phytotoxicity of CL 303,630 to several species of crops and weeds. The information would be used to alert end users to possible effects on crop plants.
4.1	**Test Substance**	CL 303,630 technical, as manufactured
4.2	**Specification**	No lot number given.
4.3	**Storage Stability**	CL 303630 has been shown to be stable at room conditions.
4.4	**Stability in Vehicle**	Not measured.
4.5	**Homogeneity in Vehicle**	Not applicable.

4.6	**Validity**	Not applicable
5	**Vehicle/Solvent**	The test substance was dissolved in acetone prior to being applied to the plants with a belt sprayer.
6	**Physical Form**	Tan powder (not described in the text)
7.1	**Test Method**	Herbicide screening methods of the testing facility.
7.2	**Justification**	CL 303630 was known to have high insecticidal activity but low herbicidal activity. The testing performed was designed to evaluate minimally herbicidal compounds.
7.3	**Copy of Method**	Not available. Herbicide screening procedures are considered to be trade secret and proprietary.
8	**Choice of Method**	Not applicable.
9	**Deviations**	Not applicable.
10.1	**Certified Laboratory**	No.
10.2	**Certifying Authority**	Not applicable
10.3	**GLP**	The study was not conducted according to the published Good Laboratory Practices.
10.4	**Justification**	Not applicable.
11.1	**GEP**	Not applicable
11.2	**Type of Facility**	Not applicable
11.3	**Justification**	Not applicable
12	**Test System**	
	Test Species:	Over 30 species of plants including:velvetleaf, redroot pigweed, common ragweed, ivyleaf morningglory, wild mustard, hairy crabgrass, barnyard grass, Italian ryegrass, yellow millet, green foxtail, sugarbeets, rape (canola), cauliflower, broccoli, soybean, cotton, sunflower, barley, lettuce, tomato, rice, snal beans, peas, bluegrass, grain sorghum, winter wheat, and field corn. The plants were all raised by the test facility.
	Dosage:	In test 89-058, CL 303630 was evaluated post emergence at 63, 125, 250, 500, and 1000 g/ha. In test 91-361, it was evaluated at 1000 g/ha preemergence. In test 91-362, it was evaluated post emergence at 500 and 1000 gr/ha. In test 92-802 it was evaluated preemergence at 250, 500, 1000, and 2000 g/ha. Application volume was the equivalent of 400 L/ha. Plants treated postemergence were at the 1 true leaf growth stage.

	Environmental conditions:	Plants were held in a greenhouse in pots containing different media, depending on the test. In 89-058 the Greenhouse mix was 81% sand, 12% silt, and 7% clay with 7% organic matter and a pH of 5.3 The Sassafras medium used in tests 91-361 and 92-802 was 68% sand, 21% silt, 11% clay, with 2% organic matter and a pH of 6.2. Metro 350, used in test 91-362 was a commercial potting mix.
	Analytical dose verification:	Verification of treatment solution concentrations was not performed. Results are based on nominal concentrations.
	Evaluation criteria	After application the plants were evaluated for phytotoxic responses according to a 0 to 9 scale, with the following gradations: 9 means 100% effect 8 means 91-99% effect 7 means 80-90% effect 6 means 65-79% effect 5 means 45-64% effect 4 means 30-44% effect 3 means 15-29% effect 2 means 6-15% effect 1 means 1-5% effect Evaluations were performed 3 weeks after application for preemergence tests and 2 weeks after application for postemergence tests.
13	**Findings**	Postemergence Tests: There was negligible crop damage from applications of CL 303630 at 500 g ai/ha or less. In test 89-058, there was very slight injury to wild mustard, sugarbeets, sunflower, and field corn. The injury was present at rates of 125 to 1000 g/ha, but was never more than 15% (3). Injury to tomato, the most sensitive species in the test, was 30-44% (4) at 1000 g/ha. In test 91-362, redroot pigweed and common ragweed were severely injured at 500 and 1000 g/ha. Preemergence Tests: In test 91-361, CL 303630 applied at the high rate of 1000 g/ha resulted in severe inury to redroot pigweed, common ragweed, and winter wheat was severe. In 92-0802 this result did not repeat at up to treatments of 2000 g/ha, so it was interpreted as test error due to poor emergence of plants, and not a treatment effect.
14	**Statistics**	Ratings were tabulated and compared as absolute values. Statements are made based on these numbers; no statistical analyses were performed.
15	**References**	None.
16	**Unpublished Data**	None.

17	**Conclusions**	The results show that CL 303630 has low herbicical activity post emergence and no herbicidal activity when applied preemergence. Two weed species showed more than a 25% effect in the postemergence test. However, because the effects occurred at high application rates compared to the insecticidal use rates, an EC25 was not calculated.
18	**Reliability**	Reliability Index of 2.

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*02.06.2005*
Materials and Methods	Applicant version is not acceptable since the study summary are not presented according to the TNsG on Dossier Preparation under directive 98/8/EC. The study are presented according to the PPP Directive, Tier II.
Results and discussion	RMS accept applicant's version.
Conclusion	Applicant's version is acceptable.
Reliability	2
Acceptability	Acceptable
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	

91/414/EEC Annex	**II**	**Toxicity to Earthworms - Sub-lethal Effects**
98/8/EC Annex	**IIIA XIII 3.2**	
PPPD Point addressed	**8.4.2**	
BPD Point addressed	**7.5.2.1**	

For Official Use Only

1.1	**Title**	Determination of the Effects of Sublethal Concentrations of AC 303,630 Applied as the Active Ingredient on Earthworm (Eisenia fetida) Growth and Reproduction [redacted]
1.2	**Report Number**	[redacted]
1.3	**Lab Report No.**	[redacted]
1.4	**Cross Reference**	8.4.2
1.5	**Authors**	[redacted]
1.6	**Date of Report**	May 09, 1995
1.7	**Published**	No
1.8	**Data Protection and Owner**	Yes; [redacted]
1.9	**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 / authorization]
2.1	**Testing Facility**	[redacted]
2.2	**Dates of Experimental Work**	December 15, 1993 - February 10, 1995
3	**Objectives**	The objective of the study was to evaluate the effects of AC 303,630 technical on earthworm growth and reproduction. Change in adult earthworm body weight and the number of juvenile earthworms present at the end of the test were used as toxicity endpoints. This study is designed to comply with the Draft International Standard ISO/DIS 11268-2, Soil quality - Effects of pollutants on earthworms (Eisenia fetida) - Part 2: Method for the determination of effects on reproduction.
4.1	**Test Substance**	AC 303,630 active ingredient as manufactured

4.2	**Specification**	Lot Number: AC 7504-59A, CAS Number: 122453-73-0 Purity = 94.5%
4.3	**Storage Stability**	Not applicable
4.4	**Stability in Vehicle**	Not applicable
4.5	**Homogeneity in Vehicle**	Not applicable
4.6	**Validity**	Not applicable
5	**Vehicle/Solvent**	Not applicable
6	**Physical Form**	Yellow solid
7.1	**Test Method**	This study is designed to comply with the Draft International Standard ISO/DIS 11268-2, Soil quality - Effects of pollutants on earthworms (Eisenia fetida) - Part 2: Method for the determination of effects on reproduction.
7.2	**Justification**	Not applicable
7.3	**Copy of Method**	Not applicable
8	**Choice of Method**	Not applicable
9	**Deviations**	The difference between the minimum and maximum weight of earthworms in the test exceeded the 100 mg difference specified in the guideline. The weight differences among treatment replicates ranged from 115 to 205 mg (mean = 162 ± 27).
10.1	**Certified Laboratory**	Yes
10.2	**Certifying Authority**	Hessisches Ministerium Für Umwelt, Energie und Bundesangelegenheiten
10.3	**GLP**	This laboratory study was carried out in accordance with the U. S. Environmental Protection Agency (EPA) Good Laboratory Practice Standards 40 CFR Part 160, Organisation for Economic Co-operation and Development (OECD), Principles of Good Laboratory Practices for the Testing of Chemicals (Paris/France, 1981), and the Chemikaliengesetz (Chemical Act) of the Federal Republic of Germany, Anlage 1 (Annex 1), dated March 14, 1990 (BGBL I 1990, p. 521). The final report contains a statement indicating that the study (test procedures, records, reports) data were collected following the above GLP standards.
10.4	**Justification**	Not applicable
11.1	**GEP**	Not applicable
11.2	**Type of Facility**	Not applicable

11.3	**Justification**	Not applicable
12	**Test System**	Earthworms (Eisenia fetida) used in the study were obtained from [redacted].
	Test species:	Earthworms selected for the study were healthy, mature, and had well-developed clitella. Earthworms were at least two months of age but not older than one year. Earthworms appearing discoloured, swollen, or of poor health were not used in the test.
	Dosage:	The test substance concentrations were 30 and 150 mg of AC 303,630 active ingredient (ai) per square meter (m^2) of artificial soil surface area. Concentrations in replicate test containers were approximately 0.84 mg and 4.2 mg ai per kg of artificial soil (dry weight), respectively. The above treatments respectively represent the equivalent of 1.0 and 5.0 times the maximumapplication rate of 300 g ai per hectare (g ai/ha). Solvent control test containers were treated with the same concentration of acetone as the active ingredient treatments while the water control test containers were treated with distilled water only. As specified in the draft ISO guideline, benomyl was tested as a reference toxicant. Benomyl was applied at a single concentration of 2.8 mg ai/kg of dry artificial soil, which corresponds to 100 mg ai/m^2 (1000 g ai/ha) applied to a 154 cm^2 test container. Each of the AC 303,630 and the control (i.e., solvent, water, and positive) treatments was replicated four times. The surface of the artificial soil was treated using a sprayer designed to simulate a 600 L/ha field application
	Evaluation criteria:	The test was divided into two portions. Adult earthworms were exposed to the test compound for a period of four weeks. After the adult exposure period, the adults were removed from the test containers and the cocoons and juvenile earthworms remained in the test containers for an additional four weeks. The total duration of the test was eight weeks. During the test, the amount of food consumed by the earthworms in each test container was approximated. The amount of food added to each test container was recorded. Four weeks after test initiation, the number of earthworms surviving the exposure period was determined. At that time, notation of morphological changes, such as discoloration, ulcers, swellings, lethargy, and lack of mobility was made. Four weeks after test initiation, the weight of the surviving earthworms was recorded.

After the removal of the adult earthworms from the test containers four weeks after test initiation, the artificial soil was replaced in the test container. The cocoons were allowed to mature and the juveniles allowed to emerge. Eight weeks after test initiation, the number of juveniles per test container was determined.

13 **Findings**

Effects on mortality: Only two of the adult worms died following the four week exposure period. One earthworm was in the acetone solvent control, while the other earthworm was in the benomyl positive control. Statistical analysis of the water and solvent control data showed no statistical difference (t-Test, $p \leq 0.05$) between the two controls. Therefore, additional statistical analyses were conducted using the pooled control data. No statistical difference was observed between the pooled control mortality level (1.3%) and the mortality level observed in either of the AC 303,630 treatments (0.0%) or the positive control (benomyl) treatment (2.5%).

Effects on earthworm weight: The mean body weight of the earthworms increased slightly during the four week exposure period in all treatment groups except the positive control group. The increase in mean body weight in the negative water control (9.9%) was significantly different (t-Test, $p \leq 0.05$) from the increased observed in the solvent control (1.8%). Therefore, additional statistical analyses were conducted using the solvent control data. The 0.3% and the 3.7% increase in body weight observed in the 300 g and the 1500 g AC 303,630 treatments, respectively, were not significantly different ($p \leq 0.05$) for the solvent control. Treatment with benomyl resulted in a statistically significant decrease in earthworm growth, in comparison to the water control, as specified in the protocol. No morphological or behavioural abnormalities were observed during the mortality and weight determinations, regardless of treatment.

Effects on juvenile production: The number of juvenile earthworms observed in the solvent control (53 ± 8) was significantly different (t-Test, $p \leq 0.05$) from the number observed in the negative water control (67 ± 8). Therefore, additional statistical analyses were conducted using the solvent control data. The number of juvenile earthworms observed in the 300 g and the 1500 g AC 303,630 treatments (82 ± 27 and 60 ± 7, respectively) was not significantly different ($p \leq 0.05$) for the solvent control. The 12 ± 3 juveniles observed in the positive (benomyl) control was significantly different from the solvent control. Treatment with benomyl resulted in a statistically significant decrease in the earthworm reproduction, in comparison to the water control, as specified in the protocol.

		Effects on food consumption: Statistical analysis of the water and solvent control data showed no statistical difference (t-Test, $p \leq 0.05$) between the two controls in the amount of food added per container. Therefore, additional statistical analyses were conducted using the pooled control data. A statistical difference was observed between the pooled control food consumption level (23.1 g) and the food consumption level observed in the 300 g ai/ha treatment (20.0 g), the 1500 g ai/ha treatment (20.1 g) and the positive control (benomyl) treatment (10.5 g). This difference in the amount of food added was equivalent to a 13.4%, a 13.0%, and a 54.5% decrease, respectively, in comparison to pooled control data. **Conclusions:** The results of this study show that exposure to AC 303,630 (active ingredient) at the equivalent of the maximum label rate (300 g ai/ha) and 5-times the maximum label rate (1500 g ai/ha) do not affect the mortality, reproduction, morphology, or change in body weight of earthworms. A decrease of approximately 0.4 g per week (13%) in the amount of food added per test container was noted in both the AC 303,630 treatments. In contrast, exposure to the positive control substance (benomyl) resulted in a significant effect on earthworm weight, the number of juveniles produced, and the food consumption. Based on these results, AC 303,630 does not appear to present a hazard to earthworms exposed to 1- or 5-times the maximum label rate.
14	**Statistics**	Statistical analysis was conducted on percent mortality, change in total replicate earthworm weight, and reproduction data. A Student's t-Test was conducted on the negative water control and the acetone solvent control data to determine the ability to pool the control data. If no statistical difference existed between the control treatments, the data were pooled and all subsequent statistical comparisons were made against the pooled data. If a statistical difference was observed between the two controls, subsequent statistical comparisons were made against the acetone solvent control. Analysis of variance was conducted on these data, along with an appropriate statistical method to determine differences between the control and individual AC 303,630 treatments (e.g., Kruskal-Wallis-H-Test, Dunn-Test, Bonferroni-Holm-U-Test, Tukey's, and Dunnett's Test).
15	**References**	Draft International Standard ISO/DIS 11268-2, Soil quality - Effects of pollutants on earthworms (*Eisenia fetida*) - Part 2: Method for the determination of effects on reproduction
16	**Unpublished Data**	None
17	**Conclusions**	Mortality of the control and vehicle control animals was much less than 10%.

18	**Reliability**	Reliability Index of 1.

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*02.03.2005*
Materials and Methods	Applicant version is not acceptable since the study summary are not presented according to the TNsG on Dossier Preparation under directive 98/8/EC. The study are presented according to the PPP Directive, Tier II.
Results and discussion	RMS accept applicant's version.
Conclusion	Applicant's version is acceptable. Other conclusions:Based on the results, AC 303,630 does not appear to present a hazard to earthworms exposed to 1- or 5-times the maximum label rate. NOEC: 0.84 mg ai/kg (on the 1-times the maximum label rate) NOEC:4.2 mg ai/kg (on the 5-times the maximum label rate)
Reliability	1
Acceptability	Acceptable
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	

Section A.7.5.2.2 Annex Point IIIA, XIII.3.2 and PT 8	Long term test with terrestrial plants	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [X] **Limited exposure [X]**	**Technically not feasible [ ]** **Scientifically unjustified [X]** **Other justification [ ]**	
Detailed justification:	The dossier contains information on the toxicity of the active substance to a wide variety of terrestrial weeds and crops (see Section A.7.5.1.3). As would be expected for an insecticide, it has minimal toxicity to terrestrial plants. Given the low of herbicidal activity of the compound additional long term testing in terrestrial plants is not justified.	
Undertaking of intended data submission [ ]	*Give date on which the data will be handed in later (Only acceptable if test or study is already being conducted and the responsible CA has agreed on the delayed 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	*25.05.2005*
Evaluation of applicant's justification	RMS agrees with the justification presented by the applicant.
Conclusion	Applicant's justification is acceptable.
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	

91/414/EEC Annex	**II**	**Effects on Birds: Acute Oral Toxicity**
98/8/EC Annex	**IIIA XIII 1.1**	
PPPD Point addressed	**8.1.1**	
BPD Point addressed	**7.5.3.1.1**	

For Official Use Only

1.1	**Title**	21-Day Acute Toxicity Test with AC 303,630 Technical in the Mallard Duck (*Anas platyrhynchos*) [redacted]
1.2	**Report Number**	[redacted]
1.3	**Lab Report No.**	[redacted]
1.4	**Cross Reference**	8.1.1/02
1.5	**Authors**	[redacted]
1.6	**Date of Report**	24 March, 1993
1.7	**Published**	No
1.8	**Data Protection and Owner**	Yes; [redacted]
1.9	**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 / authorization].
2.1	**Testing Facility**	[redacted]
2.2	**Dates of Experimental Work**	31 March, 1992 - 21 April, 1992
3	**Objectives**	The objective of the study was to determine the acute oral LD_{50}, and no observable effect level for mortality of AC 303,630 technical administered to mallard ducks (*Anas platyrhynchos*).
4.1	**Test Substance**	AC 303,630 active ingredient as manufactured
4.2	**Specification**	Lot Number AC 7504-59A (CAS Number 122453-73-0), Purity = 94.5%
4.3	**Storage Stability**	Test substance expiration data -- February 1994
4.4	**Stability in Vehicle**	Not applicable (single dose preparation)

4.5	**Homogeneity in Vehicle**	See Section 4.4
4.6	**Validity**	Not applicable
5	**Vehicle/Solvent**	The test substance was dissolved in acetone prior to being dispensed into gelatin capsules. The acetone was completely evaporated before the capsules were given to the test birds.
6	**Physical Form**	Tan powder
7.1	**Test Method**	The effects of AC 303,630 on mallard ducks were tested in a laboratory study according to the U.S. Environmental Protection Agency's Guideline Number 71-1.
7.2	**Justification**	Not applicable.
7.3	**Copy of Method**	Not applicable.
8	**Choice of Method**	Not applicable.
9	**Deviations**	No deviations from the guidelines were noted.
10.1	**Certified Laboratory**	Not applicable.
10.2	**Certifying Authority**	Not applicable.
10.3	**GLP**	This laboratory study was carried out in accordance with the U.S. Environmental Protection Agency Good Laboratory Practice Standards 40 CFR Part 160.
10.4	**Justification**	Not applicable.
11.1	**GEP**	Not applicable.
11.2	**Type of Facility**	Not applicable.
11.3	**Justification**	Not applicable.
12	**Test System**	Twenty-one-week-old mallard ducks were selected for use in the test and were exposed to the test substance.
	Test species:	The test birds used in this test were acquired from [redacted] The test birds were 18 weeks of age upon receipt at the testing site.
	Dosage:	The test was conducted using eight groups of 10 ducks. Nominal dosages were 0, 1, 2, 4, 8, 16, 32, 64, and 128 mg test substance/kg body weight.
	Analytical Dose Verification:	No dose verification was performed. The test substance was administered in capsules prepared on the day of dosing.

	Evaluation Criteria:	Test birds were observed for 21 days after dosing. Birds were observed daily for mortality and changes in clinical observations. Body weights and feed consumption were measured periodically during the test. All birds that died on test and four survivors from each test group, if possible, underwent complete post-mortem examinations.
13	**Findings**	No mortalities were recorded in the control group or in the 1 or 2 mg/kg treatment groups throughout the test. Mortality in the remaining treatment groups receiving AC 303,630 technical was: 1/10 in the 4 mg/kg group, 8/10 in the 8 mg/kg group, 7/10 in the 16 mg/kg group, 9/10 in the 32 mg/kg group, and 10/10 in the 64 and 128 mg/kg groups. No clinical signs of toxicity were noted in the control group or the 1 mg/kg treatment group throughout the test. Clinical signs of toxicity noted in the remaining groups included dyspnea, loose green excreta, loose chalky excreta convulsions, wing-beat convulsions, and decreased feed consumption. No significant reductions in body weights were noted throughout the test in animals receiving 16 mg/kg or less. No statistical analyses were possible for changes in body weights for test birds receiving 32, 64, and 128 mg/kg groups because of the degree of mortality in these groups. Most of the gross pathological findings were noted in birds found dead early in the morning after lying dead for an undetermined (but < 14 hr) amount of time during the night. All the findings, with the exception of firm pectoral muscles may have been the result of postmortem autolysis, and therefore were not considered to be compound-related. A no-observable-effect level, based on mortality and clinical signs of toxicity, was 1 mg AC 303,630/kg body weight. AC 303,630 was determined to be highly toxic to mallard ducks with an acute oral LD_{50} of 10.3 mg AC 303,630 technical/kg body weight and a 95% confidence interval of 7.0 to 15.1 mg/kg.
	Statistics	The median lethal dose (LD_{50}) was calculated according to the simplified method of Litchfield and Wilcoxon. Body weight and feed consumption data were analyzed using analysis of variance methods.
15	**References**	Litchfield, J.T., Jr. and F. Wilcoxon. 1949. A simplified method of evaluating dose-effect experiments. The Journal of Pharmacology and Experimental Therapeutics. Vol. 96, No. 2. SPSS PC+™, Ver. 4.0, SPSS Inc., 444 Michigan Avenue, Chicago, IL 60611
16	**Unpublished Data**	None.

17	**Conclusions**	The compound was very highly toxic to mallards, a result which is in agreement with testing in other species. Mortality of the control birds was less than 10%.
18	**Reliability**	Reliability Indicator of 1.

	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*02.03.2005*
Materials and Methods	Applicant version is not acceptable since the study summary are not presented according to the TNsG on Dossier Preparation under directive 98/8/EC. The study are presented according to the PPP Directive, Tier II.
Results and discussion	RMS accept applicant's version.
Conclusion	Applicant's version is acceptable. LD_{50}: 10.3 mg a.i./kg body weight NOEL: 1 mg a.i./kg body weight
Reliability	1
Acceptability	Acceptable
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	

91/414/EEC Annex	**II**	**Effects on Birds: Acute Oral Toxicity**
98/8/EC Annex	**IIIA XIII 1.1**	
PPPD Point addressed	**8.1.1**	
BPD Point addressed	**7.5.3.1.1**	

			For Official Use Only
1.1	**Title**	21-Day Acute Toxicity Test with AC 303,630 Technical in the Northern Bobwhite (*Colinus virginianus*) [redacted]	
1.2	**Report Number**	[redacted]	
1.3	**Lab Report No.**	[redacted]	
1.4	**Cross Reference**	8.1.1/01	
1.5	**Authors**	[redacted]	
1.6	**Date of Report**	24 March, 1993	
1.7	**Published**	No	
1.8	**Data Protection and Owner**	Yes; [redacted]	
1.9	**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 / authorization].	
2.1	**Testing Facility**	[redacted]	
2.2	**Dates of Experimental Work**	31 March, 1992 - 21 April, 1992	
3	**Objectives**	The objective of the study was to determine the acute oral LD_{50}, and no observable effect level for mortality of AC 303,630 technical administered to northern bobwhite (*Colinus virginianus*).	
4.1	**Test Substance**	AC 303,630 active ingredient as manufactured	
4.2	**Specification**	Lot Number AC 7504-59A (CAS Number 122453-73-0), Purity = 94.5%	
4.3	**Storage Stability**	Test substance expiration data -- February 1994	
4.4	**Stability in Vehicle**	Not applicable (single dose preparation)	

4.5	**Homogeneity in Vehicle**	See Section 4.4
4.6	**Validity**	Not applicable
5	**Vehicle/Solvent**	The test substance was dissolved in acetone prior to being dispensed into gelatin capsules. The acetone was complete evaporated before the capsules were given to the test birds.
6	**Physical Form**	Tan powder
7.1	**Test Method**	The effects of AC 303,630 on northern bobwhite were tested in a laboratory study according to the U.S. Environmental Protection Agency's Guideline Number 71-1.
7.2	**Justification**	Not applicable.
7.3	**Copy of Method**	Not applicable.
8	**Choice of Method**	Not applicable.
9	**Deviations**	No deviations from the guidelines were noted.
10.1	**Certified Laboratory**	Not applicable.
10.2	**Certifying Authority**	Not applicable.
10.3	**GLP**	This laboratory study was carried out in accordance with the U.S. Environmental Protection Agency Good Laboratory Practice Standards 40 CFR Part 160.
10.4	**Justification**	Not applicable.
11.1	**GEP**	Not applicable.
11.2	**Type of Facility**	Not applicable.
11.3	**Justification**	Not applicable.
12	**Test System**	Twenty-seven -week-old northern bobwhite were selected for use in the test and were exposed to the test substance.
	Test species:	The test birds used in this test were acquired from [redacted]. The test birds were 24 weeks of age upon receipt at the testing site.
	Dosage:	The test was conducted using eight groups of 10 bobwhite. Nominal dosages were 0, 1, 2, 4, 8, 16, 32, 64, and 128 mg test substance/kg body weight.
	Analytical Dose Verification:	No dose verification was performed. The test substance was administered in capsules prepared on the day of dosing.

	Evaluation Criteria:	Test birds were observed for 21 days after dosing. Birds were observed daily for mortality and changes in clinical observations. Body weights and feed consumption were measured periodically during the test. All birds that died on test and four survivors from each test group, if possible, underwent complete post-mortem examinations.
13	**Findings**	No mortalities were recorded in the control group or in the 1, 2, 4, and 8 mg/kg treatment groups throughout the test. Mortality in the remaining treatment groups receiving AC 303,630 technical was: 1/10 in the 16 mg/kg group, 4/10 in the 32 mg/kg group, 9/10 in the 64 mg/kg group, and 10/10 in the 128 mg/kg group. No clinical signs of toxicity were noted in the control group or the 1, 2, 4, and 8 mg/kg treatment groups throughout the test. Clinical signs of toxicity noted in the remaining groups included loose green excreta, loose chalky excreta, lethargy, decreased activity, wing-beat convulsions, and decreased feed consumption. Body weights showed significant reductions after 3 days on test in the 32, 64, and 128 mg/kg groups. Most of the gross pathological findings were noted in birds found dead early in the morning after lying dead for an undetermined (but < 14 hr) amount of time during the night. All the findings, with the exception of firm pectoral muscles and the green contents of the gizzard, may have been the result of postmortem autolysis, and therefore were not considered to be compound-related. A no-observable-effect level, based on mortality and clinical signs of toxicity, was 8 mg AC 303,630/kg body weight. AC 303,630 was determined to be highly toxic to northern bobwhite with an acute oral LD_{50} of 34 mg AC 303,630 technical/kg body weight and a 95% confidence interval of 24 to 49 mg/kg.
14	**Statistics**	The median lethal dose (LD_{50}) was calculated according to the simplified method of Litchfield and Wilcoxon. Body weight and feed consumption data were analyzed using analysis of variance methods.
15	**References**	Litchfield, J.T., Jr. and F. Wilcoxon. 1949. A simplified method of evaluating dose-effect experiments. The Journal of Pharmacology and Experimental Therapeutics. Vol. 96, No. 2. SPSS PC+™, Ver. 4.0, SPSS Inc., 444 Michigan Avenue, Chicago, IL 60611
16	**Unpublished Data**	None.

17	**Conclusions**	The compound was very highly toxic to the bobwhite, a result that is consistent with tests in other species. Mortality of control birds was less than 10%.
18	**Reliability**	Reliability Index of 1.

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*02.06.2005*
Materials and Methods	Applicant version is not acceptable since the study summary are not presented according to the TNsG on Dossier Preparation under directive 98/8/EC. The study are presented according to the PPP Directive, Tier II.
Results and discussion	RMS accept applicant's version.
Conclusion	Applicant's version is acceptable. LD50: 34 mg a.i./kg body weight NOEL: 8 mg a.i./kg body weight
Reliability	1
Acceptability	Acceptable
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	

91/414/EEC Annex	**II**	**Effects on Birds: Acute Oral Toxicity (LD_{50}) with a Metabolite, CL 312094**
98/8/EC Annex	**IIIA XIII 1.1**	
PPPD Point addressed	**8.1.1**	
BPD Point addressed	**7.5.3.1.1**	

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1.1	**Title**	14-Day Acute Toxicity Test with AC 312,094 Technical in Northern Bobwhite (*Colinus virginianus*) [redacted]
1.2	**Report Number**	[redacted]
1.3	**Lab Report No.**	[redacted]
1.4	**Cross Reference**	Not applicable
1.5	**Authors**	[redacted]
1.6	**Date of Report**	December 19, 1995
1.7	**Published**	No
1.8	**Data Protection and Owner**	Yes; [redacted]
1.9	**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 / authorization].
2.1	**Testing Facility**	[redacted]
2.2	**Dates of Experimental Work**	July 24, 1994 – August 14, 1994
3	**Objectives**	The objective of this study was to determine the acute oral toxicity (LD_{50}) and the no observable effect level (NOEL) for mortality, if possible, of orally administered AC 312,094 to northern bobwhites (*Colinus virginianus*).
4.1	**Test Substance**	AC 312,094 (also known as CL 312094)
4.2	**Specification**	Lot Number AC 8698-67A, Purity = 96.3% AC 312,094
4.3	**Storage Stability**	Stable under normal room temperatures
4.4	**Stability in Vehicle**	Dosing solutions were analyzed during the time interval that birds were dosed.

4.5	**Homogeneity in Vehicle**	See Section 4.4
4.6	**Validity**	Not applicable
5	**Vehicle/Solvent**	The test substance was dissolved in corn oil prior to being administered via gavage to the test birds.
6	**Physical Form**	White powder
7.1	**Test Method**	This test was based on U.S. EPA Guideline Number 40 CFR 158.145, Series 71-1.
7.2	**Justification**	Not applicable.
7.3	**Copy of Method**	Not applicable.
8	**Choice of Method**	Not applicable.
9	**Deviations**	No deviations from the guidelines were noted.
10.1	**Certified Laboratory**	Not applicable.
10.2	**Certifying Authority**	Not applicable.
10.3	**GLP**	This laboratory study was carried out in accordance with the U.S. Environmental Protection Agency Good Laboratory Practice Standards 40 CFR Part 160 and the OECD Good Laboratory Practices in the Testing of Chemicals ISBN-92-64-12367-9.
10.4	**Justification**	Not applicable.
11.1	**GEP**	Not applicable.
11.2	**Type of Facility**	Not applicable.
11.3	**Justification**	Not applicable.
12	**Test System**	Test species: Sixteen-week-old bobwhite were selected for use in the test and were exposed to the test substance. The test birds used in this test were acquired from [redacted] Dosage: The test was conducted using six groups of 10 bobwhite. Nominal dosages were 15, 50, 160, 500, and 1600 mg ai/kg body weight.