

Are appropriate life-stages studied?	Yes
Are the experimental conditions relevant for the tested species?	Yes
Is the exposure duration relevant and appropriate for the studied endpoints and species?	Yes
If recovery is studied, is this relevant for the framework for which the study is evaluated?	Not applicable
Concluding weight of evidence/proposed action	R1, C1
Type of information (Fully acceptable, supporting information, not applicable)	Fully acceptable
Consideration/concluding score	NOEC of 50.8 mg/kg and EC10 of 43.9 mg/kg can be used for risk assessment

Reference: KCP 10.4.1.1/01

Report 5.1.2.e (2009) - Lambda-cyhalothrin CS (A12690B) – Sublethal toxicity to the earthworm *Eisenia fetida*, BioChem Agrar GmbH, Gerichshain, Germany, 09 10 48 086 S, unpublished. (Syngenta File No. A12690B_11225).

Guideline(s): OECD Guideline for testing of chemicals No. 222 (adopted 13 April 2004): Earthworm Reproduction Test (*Eisenia fetida*/*Eisenia andrei*)

Deviations: No

GLP: Yes

Acceptability: Yes

Duplication (if vertebrate study) No

Executive Summary

In a chronic toxicity test in which earthworms (*Eisenia fetida*) were exposed to A12690B the NOEC based on biomass and reproductive performance of the worms was determined to be 45 and 30 mg A12690B/kg soil dry weight, respectively.

Since no change of reproduction compared to the control greater than 50% was observed, the EC₅₀ could not be calculated, but it can be concluded that the EC₅₀ > 60 mg /kg soil dry weight, the highest concentration tested.

Materials

Test Material A12690B
 Lambda-cyhalothrin SC (100)

Lot/Batch #: BSN7C2901

Actual content of active ingredients:	Lambda-cyhaltrin: 96.8 g/L corresponding to 9.14 % w/w
Description:	Off-white opaque liquid
Stability of test compound:	Stable under standard conditions.
Reanalysis/Expiry date:	End of March 2010
Density:	1059 kg/m ³
Treatments	
Test rates:	6.4, 12.7, 25.4, 50.8, 101.7 mg A12690B/kg soil d.w.
Control:	Untreated substrate irrigated with deionised water only
Toxic standard:	Nutdazim 50 FLOW (carbendazim, SC 500) was tested at concentrations of 5 and 10 mg product/kg soil dry weight (BioChem project No.: TER-R 09 10 48 001, dated 17 July 2009).
Test organisms	
Species:	<i>Eisenia fetida</i> (Savigny, 1826) (subspecies <i>Eisenia andrei</i> Bouché, 1927)
Age and weight range at test start:	Adult worms, approximately 3 months old with clitellum. Weight 317 – 478 mg/worm
Source:	Reared at test facility, original breeding animals from “W. Neudorff GmbH KG”, An der Mühle 3, 31860 Emmerthal, Germany)
Feeding:	Air-dried, finely ground horse manure
Test design	
Vessels:	Plastic vessels (about 18.3 × 13.6 × 6.4 cm) with lids pervious to air and light.
Substrate:	Artificial soil comprising 10% sphagnum peat, 20 % kaolinite clay, 69.5 % industrial quartz sand (> 50% of the particles between 0.05 mm and 0.2 mm) and 0.5% calcium carbonate. 810 g wet weight soil, corresponding to about 600 g dry weight, of artificial soil was added to each test vessel.
Replication:	4 per treatment group, 8 in control group
No. of worms/arena :	10
Duration of test:	8 weeks
Environmental test conditions	
Temperature:	18.6 – 21.9 °C
pH of soil:	test start: 6.06 – 6.10 test end: 5.70 – 5.89
Water content of soil:	test start: 34.8 – 35.0 % (equivalent to 54.3 – 54.6 % of WHC) test end: 34.6 – 35.0 % (equivalent to 54.0 – 54.6 % of WHC)
Photoperiod:	light : dark = 16 h : 8 hr (570 lux)

Study Design and Methods

Experimental dates: 01 September 2009 – 27 October 2009

Approximately 24 hours before test start, dry artificial soil was pre-moistened by adding deionised water to obtain approximately half of the final water content. The worms were acclimatised in a separate batch of the untreated artificial substrate (mixed with horse manure) for one day before test start.

At test start the artificial soil was mixed with quantities of the test item solution necessary to achieve the required test concentrations and final nominal water content of 40-60 % of WHC. The test vessels were filled with 810 g wet weight (600 g dry weight) of soil. The acclimatised test animals were weighed and randomly placed onto the test substrate (10 animals per test vessel).

One day after application, 5 g dried and ground horse manure was scattered on the soil surface of each test vessel. This was sprinkled with 5 mL deionised water. The feeding interval was weekly during the first four weeks of the test. The weekly amount of manure (up to 5 g) depended on feeding activity.

After four weeks, the adult worms were removed from the test vessels, and mortality and the body weight of the surviving worms were determined. After all of the adult worms had been removed, the soil in each vessel was mixed with 5 g horse manure. Four weeks later, the number of surviving juveniles and any morphological alterations were recorded. Observations of behavioural and pathological symptoms (including the feeding activity) were observed weekly.

The mortality, biomass, and reproduction results were analysed with the software ToxRat Professional 2.10 (RATTE 2009). Fisher's Exact Binomial Test with Bonferroni Correction and the Dunnett-test were used to compare the control with the independent test item groups. For statistical evaluation of the biomass change, the changed mean fresh weight of surviving worms per replicate was used.

Results and Discussion

Mortality and fecundity are summarised in the table below.

Table A 42: Effect of A12690B on mortality, growth and reproduction of *Eisenia fetida*

Endpoints	Treatment groups (mg A12690B/kg soil dry weight)					
	Control	6.4	12.7	25.4	50.8	101.7
Mean adult mortality at 28 days (%)	0	0	0	0	2.5	2.5
Mean % biomass change of adults from 0-28 days	71.2	68.8	64.7	66.5	61.9	38.8*
Mean number of juveniles after 8 weeks	94.1	90.5	106.0	87.5	73.8	5.0*
Coefficient of variation for reproduction (cv %)	15.5	16.4	18.5	17.5	17.2	84.9
% difference in reproduction relative to the control	-	-3.9	12.6	-7.0	-21.6	-94.7
NOEC	50.8 mg A12690B/kg soil dry weight					
EC ₅₀	63.8 mg A12690B/kg soil dry weight					

*statistically significant (Dunnett-t-test, $p \leq 0.05$, one-sided smaller)

No statistically significant differences between the control and test item were calculated for mortality (Fisher's Exact Binomial Test with Bonferroni Correction)

d.w.: dry weight (of artificial soil), cv %: coefficient of variation

Validity criteria

The validity criteria for the control group were met.

The adult mortality at 4 weeks was $\leq 10\%$ (0 % after 4 weeks)

The number of juveniles per replicate was ≥ 30 (79 – 112)

The coefficient of variation for reproduction was $\leq 30\%$ (being 15.5%)

Conclusions

In a chronic toxicity test in which earthworms (*Eisenia fetida*) were exposed to A12690B the NOEC based on biomass and reproductive performance of the worms was determined to be 50.8 mg A12690B/kg soil dry weight, respectively.

The EC₅₀ was determined to be 63.8 mg /kg soil dry weight.

(5.1.2.e 2009)

A 2.4.1.2 KCP 10.4.1.2 Earthworms - field studies

Higher-tier data were not collected as the risk assessment above indicates acceptable risk.

A 2.4.2 KCP 10.4.2 Effects on non-target soil meso- and macrofauna (other than earthworms)

A 2.4.2.1 KCP 10.4.2.1 Species level testing

The studies previously submitted in the EU were summarised in the DAR and its addenda therefore additional study summaries are not repeated here.

A 2.4.2.2 KCP 10.4.2.2 Higher tier testing

Higher-tier data were not collected as the risk assessment above indicates acceptable risk.

A 2.5 KCP 10.5 Effects on soil nitrogen transformation

The studies previously submitted in the EU were summarised in the DAR and its addenda therefore additional study summaries are not repeated here.

A 2.6 KCP 10.6 Effects on terrestrial non-target higher plants

A 2.6.1 KCP 10.6.1 Summary of screening data

The studies previously submitted in the EU were summarised in the DAR and its addenda therefore additional study summaries are not repeated here.

A 2.6.2 KCP 10.6.2 Testing on non-target plants

Higher-tier data were not collected as the risk assessment above indicates acceptable risk.

A 2.6.3 KCP 10.6.3 Extended laboratory studies on non-target plants

Higher-tier data were not collected as the risk assessment above indicates acceptable risk.

A 2.7 KCP 10.7 Effects on other terrestrial organisms (flora and fauna)

No further data on other terrestrial organisms is required.

A 2.8 KCP 10.8 Monitoring data

No monitoring studies are needed for ecotoxicological purposes as an acceptable risk has been identified for its proposed uses.