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Attention: (8e) Coordinator
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
401 M Street, SW
Washington, DC 20460

~~CONFIDENTIAL~~

Ladies and Gentlemen:

Notice in Accordance to TSCA Section 8(e) - Preliminary results of an early-life stage (ELS) study in Rainbow Trout.

BASF Corporation is submitting preliminary results of an early-life stage (ELS) study in Rainbow trout with a developmental fungicide (substituted benzylether), conducted by BASF Aktiengesellschaft, Ludwigshafen, Germany. Shipments totaling approximately 1.5 kilograms active ingredient have been shipped to the U.S. since 1995.

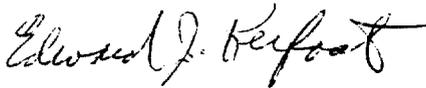
The NOAEC was determined to be 0.00316 mg/l.

Any reports or additional information that we receive will be forwarded to the Agency and Material Safety Data Sheets will be updated with this preliminary information.

If you have any questions, please feel free to call me at (734) 324-6207.

Very Truly Yours,

BASF Corporation



Edward J. Kerfoot, Ph.D.
Director, Toxicology and Product Regulations

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STUDY TITLE

Test Report

**BAS 500 F - Early Life-Stage
Toxicity Test on the Rainbow Trout
(Oncorhynchus mykiss WALBAUM 1792)**

DATA REQUIREMENT

OECD 210, adopted July 17, 1992 and
(U.S.) EPA-FIFRA 72-4 (a), 1982

AUTHOR

Dr.rer.nat. S. Zok (Study Director)

STUDY COMPLETED ON

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PERFORMING LABORATORY

Department of Toxicology of
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LABORATORY PROJECT IDENTIFICATION

52F0494/965141

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1. SUMMARY

A test on early life-stage toxicity of **BAS 500 F** on embryos, larvae and young fish of the rainbow trout (*Oncorhynchus mykiss* WALBAUM 1792) was conducted by the Laboratory for Wildlife- and Fish Toxicology of the Department of Toxicology of BASF Aktiengesellschaft, 67056 Ludwigshafen, FRG, for a period of 98 days from February 17, 1998 to May 26, 1998, following the OECD 210 and the EPA-FIFRA Guidelines.

The study was performed under flow-through, unaerated conditions with 5 concentrations of test compound and a dilution water control (each comprising four replications). The temperature was maintained generally at 10°C. The dilution water was unchlorinated drinking water obtained from the municipal water works and was adjusted to a hardness of approximately 0.5 mmol/L (approx. 50 mg/L CaCO₃) with deionized water.

Nominal concentrations of the test compound were:

0.0 mg/L (Control), 0.0001, 0.000316, 0.001, 0.00316 and 0.01 mg/L. The concentrations of the test substance were not adjusted for the reported purity of the active ingredient in the test substance. A viability control with dilution water only, was included for the initial 14 days of the study to monitor the fertilization and survival rates.

The mean analytically determined concentration values of the test compound in the test water were within a range of 60.7 – 80.6% of the nominal concentrations. Therefore the effect concentrations based on the mean of the analytically determined concentrations are reported additionally.

Mean measured concentrations were (% of nominal):

0.0001 mg/L = 80.6%, 0.000316 mg/L = 65.8%; 0.001 mg/L = 60.7%; 0.00316 mg/L = 74.3% and 0.01 mg/L = 64.2% of the nominal values.

Unfertilized eggs and sperm were obtained from a trout breeding farm in Germany. Eggs used in the study were fertilized February 17, 1998 and placed in the exposure chambers approximately 1.5 - 2 hours after fertilization in the BASF laboratory. All embryos appeared to be in good condition at the beginning of the study. The survival rate in the concurrent viability control (mean of 200 embryos) after 14 days was 78%.

Measured and/or determined biological parameters were the mortality of the embryos at the beginning of hatch (day 32), the number of surviving healthy larvae at the end of hatch (day 38) and termination of swim-up (day 56) and of the young trouts at the conclusion of the study (day 98), time to hatch and swim-up, toxic signs (symptoms), the weight (wet weight) and the total length (from tip of the snout to the end of the caudal fin) of surviving fish.

The results were as follows:

– Survival

The survival at start of hatch (day 0-32) was significantly lower in the concentration groups 0.000316 mg/L ($p \leq 0.01$), 0.001 mg/L ($p \leq 0.05$) and 0.00316 mg/L ($p \leq 0.05$) in comparison to the control group. Survival at the end of hatch (day 0 – 38) was significantly decreased in comparison to the control in the 0.000316 mg/L group ($p \leq 0.05$). However, the decrease was obviously not dependent on the test substance concentration and there was no significant effect in the highest concentration group 0.01 mg/L. The effects were therefore considered not to be caused by the test substance.

In the highest test concentration (0.01 mg/L) all fish died until day 44. This was considered to be a clear substance related effect. No significant deviation in survival from the control group was seen in the concentration groups 0.001 and 0.00316 mg/L until the end of the study (day 98). Therefore the significant decrease in survival for the time period 0-56 days observed in the concentration group 0.000316 mg/L was considered not to be test substance related.

In conclusion, the highest concentration 0.01 mg/L killed the larvae quantitatively before swim-up.

The NOAEC²⁾ for survival is 0.00316 mg/L (nominal concentration) and 0.0023 mg/L (based on the mean analytically determined concentration), the LOAEC³⁾ is 0.01 mg/L (nominal concentration) and 0.0064 mg/L (based on the mean analytically determined concentration).

– Time to hatch and swim-up

The larvae started hatching nearly simultaneously at day 34 in the two lower test groups (0.0001 and 0.000316 mg/L) and in the control group. Hatch was completed on day 38. In the three higher test groups (0.001 - 0.01 mg/L) start of hatching was on days 32 and 33 and end of hatching was on day 38. The slightly earlier start of hatch in the three higher concentration groups was not considered to be a substance related effect.

The onset and end of swim-up are recorded for all test groups in Appendix A, Table 4. The first swim-up was observed at day 51 in the control group and at days 48 – 50 in the concentration groups. The swim-up was completed at day 54 in the concentration

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groups 2 and 3 (0.000316 and 0.001 mg/L) and at day 56 in all other concentration groups with surviving larvae (0.0001 and 0.00316 mg/L) and in the control group. The slightly earlier start of swim-up in the concentration groups 3 and 4 correlated with the earlier hatching in these concentration groups and was considered not to be a substance related effect.

– Toxic signs (symptoms) and abnormalities

The control group showed reduced or no food consumption from day 76 onward in all replicates which was considered to be probably caused by an infection. This resulted in a poor general condition of the animals of the control group at the end of the study. Therefore the control group of a range finding study which was conducted in parallel with another test substance was used additionally for the evaluation of the results from the concentration groups.

- The larvae of the highest concentration group (0.01 mg/L) showed apathy and partly a narcotic state and a distended yolk-sac for a period of 6 days after the end of hatch until 100% of the larvae of this group had died. In the other concentration groups effects were limited to single individuals and are judged not to be compound-related. The surviving animals of the concentration groups did not show any external abnormalities at the end of the study.

Thus, the NOAEC for sublethal effects is 0.00316 mg/L (nominal concentration) and 0.0023 mg/L (based on the mean analytically determined concentration), the LOAEC is 0.01 mg/L (nominal concentration) and 0.0064 mg/L (based on the mean analytically determined concentration).

– Body weight and length

The control group was adversely affected probably by an infection. Therefore the food uptake was reduced during the last three weeks of exposure in the control group. The body weight and length of the control group had therefore statistically significantly decreased in comparison to the concentration group ($p \leq 0.01$) and was considered to be inadequate for a statistical evaluation. The body weight and length of a range finding test conducted in parallel to this study were used additionally for the evaluation of effects. The development of the mean body weight or length measured in any concentration group with surviving fish at the end of the study was not impaired in comparison to the control group of the parallel study.

Thus, the NOAEC for the impairment of body weight and length was ≥ 0.00316 mg/L (nominal concentration) and 0.0023 mg/L (based on the mean analytically determined concentration), the highest concentration with surviving animals tested in this study.

In conclusion, under the conditions of this study, the overall NOAEC (no observed adverse effect concentration) was 0.00316 mg/L (nominal concentration) and 0.0023 mg/L (based on the mean analytically determined concentration) and the lowest concentration with adverse effects (LOAEC) was 0.01 mg/L (nominal concentration) and 0.0064 mg/L (based on the mean analytically determined concentration).

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